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IN THE

Supreme Court of the United States

OCTOBER TERM, 1995

THE AMERICAN LEGION,
BILL ATWELL, CAROL DELANEY-RIDOLFI,
JULIO GONZALEZ, MAREL J. MACKI,
BEVERLY NEHMER and PAUL SUTTON,
Petitioners,

v.

JESSE BROWN, SECRETARY DEPARTMENT OF VETERANS AFFAIRS; DONNA E. SHALALA, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES; DAVID SATCHER, DIRECTOR, CENTERS FOR DISEASE CONTROL; RICHARD J. JACKSON, DIRECTOR, NATIONAL CENTER FOR ENVIRONMENTAL HEALTH; UNITED STATES OF AMERICA,
Respondents.

Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

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PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

A federal statute requires the Secretary of Veterans Affairs to conduct an epidemiological study of the long term adverse health effects of exposure to Agent Orange on those Vietnam veterans who are more likely to have been exposed, and, if it finds an association between such exposure and various diseases, to provide disability and/or death compensation for Vietnam veterans suffering from such diseases. The statute requires the Secretary to conduct the study at least until after he has submitted his first report to Congress describing the "results thus far obtained under the study." The Secretary canceled the study, before collecting and reporting to Congress any health results, based on scientists' opinion that it was impossible to conduct the study in a scientifically valid manner unless the accuracy of the military records to be used in the study could be independently verified. Petitioners do not challenge respondents' inability to provide independent verification.

The questions are:

1. a. Whether, applying the traditional tools of statutory construction, Congress clearly intended that the initial "results" the Secretary was mandated by the Veterans' Health Programs Extension and Improvement Act of 1979 to report prior to being authorized to cancel the study were results as to adverse health effects, or merely whatever progress the study had made.

1. b. If Congress' intent is "ambiguous" as to statutes enacted to benefit veterans, which canon of construction is to prevail: the rule most recently announced in *Brown v. Gardner*, 115 S. Ct. 552, 555 (1994) "that interpretive doubt is to be resolved in the veteran's favor" or the rule of *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 (1984) that courts are to defer to the agency's interpretation, if reasonable.

2. Whether a federal agency decision based solely on facts and conclusory scientists' opinion, without consideration of scientific principles or any explanation of how the agency or the scientists reasoned from the facts found to the opinion reached, is "arbitrary and capricious" under *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 167-68 (1962) and *Baltimore Gas and Electric v. Natural Resources Defense Council*, 462 U.S. 87, 103, 105-6 (1983).

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PETITION FOR A WRIT OF CERTIORARI

The American Legion ("Legion"), Bill Atwell, Carol Delaney-Ridolfi, Julio Gonzalez, Marel J. Macki, Beverly Nehmer and Paul Sutton hereby petition for a writ of certiorari to review the judgment and opinion of the United States Court of Appeals for the District of Columbia Circuit, entered on April 25, 1995, in the consolidated appeals of The American Legion, Julio Gonzalez and Paul Sutton v. Jesse Brown, Secretary, Department of Veterans Affairs; Donna E. Shalala, Secretary, Department of Health and Human Services; David Satcher, Director, Centers for Disease Control; Richard J. Jackson, Director, National Center for Environmental Health; and United States of America and Bill Atwell, Carol Delaney-Ridolfi, Marel J. Macki, and Beverly Nehmer v. the same respondents.

OPINIONS BELOW

The opinion of the United States District Court for the District of Columbia granting the government's motion for summary judgment against the Legion, individual veterans and veterans' surviving spouses (App. 30a-47a)[1] is reported at 827 F. Supp. 805. The opinion of the United States Court of Appeals for the District Columbia affirming the District Court (App. 1a-27a) is reported at 54 F.3d 789.

JURISDICTION

The judgment of the court of appeals was entered on April 25, 1995. (App. 1a) On June 19, 1995, the Chief Justice extended the time for filing a petition for writ of certiorari until August 23, 1995. The jurisdiction of this Court is invoked pursuant to 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The most central provisions of section 307 of the Veterans' Health Programs Extension and Improvement

[1] All citations to "App. ——" refer to the Appendix filed contemporaneously herewith pursuant to United States Supreme Court Rule 14.1(k).

Act of 1979, as amended, 38 U.S.C.A. § 527 note (1991), provide as follows:

"(a)(1)(A) The Administrator of Veterans' Affairs shall design a protocol for and conduct an epidemiological study of any long-term adverse health effects in humans of service in the Armed Forces of the United States in the Republic of Vietnam during the period of the Vietnam conflict as such health effects may result from exposure to phenoxy herbicides (including the herbicide known as Agent Orange) and the class of chemicals known as the dioxins produced during the manufacture of such herbicides.

* * * *

"(2)(A)(i) The study conducted pursuant to paragraph (1) shall be conducted in accordance with a protocol approved by the Director of the Office of Technology Assessment.

"(ii) The Director shall monitor the conduct of such study in order to assure compliance with such protocol.

"(B)(i) Concurrent with the approval or disapproval of any protocol under subparagraph (A)(i), the Director of the Office of Technology Assessment shall submit to the appropriate committees of the Congress a report explaining the basis for the Director's action in approving or disapproving such protocol and providing the Director's conclusions regarding the scientific validity and objectivity of such protocol.

* * * *

"(3) The study conducted pursuant to paragraph (1) shall be continued for as long after the submission of the first report under subsection (b)(2) as the Administrator may determine reasonable in light of the possibility of developing through such study significant new information on the long-term adverse health effects of exposure to dioxins.

* * * *

"(b)(2) Not later than twenty-four months after the date of the approval of the protocol pursuant to

subsection (a)(2)(A)(i) and annually thereafter, the Administrator shall submit to the appropriate committees of the Congress a report containing (A) a description of the results thus far obtained under the study conducted pursuant to such subsection, and (B) such comments and recommendations for administrative or legislative action, or both, as the Administrator considers appropriate in light of such results.

"(3) Immediately after the submission of each report under paragraph (2), the Administrator, based on the results described in such report and the comments and recommendations included therein and any other available pertinent information, shall evaluate the need for any amendments to regulations, prescribed pursuant to section 5 of the Veterans' Dioxin and Radiation Exposure Compensation Standards Act, [section 5 of Pub.L. 98-542, set out as a note under section 1154 of this title] for the resolution of claims for service connection based on the exposure specified in subsection (a)(1)(A) of such section. . . .

"(4) The first report submitted under paragraph (2) shall include the Administrator's recommendation, and reasons therefor, with respect to whether the authority to provide care and services under and by virtue of section 610(a)(5) of title 38, United States Code [now section 1710(a)(5) of this title], should be extended beyond the expiration period specified by section 610(e)(3) of such title [now section 1710(e)(3) of this title]."

* * * *

STATEMENT OF THE CASE

A. The Government's Breach Of Commitment And Injury To Vietnam Veterans Exposed To Agent Orange

In 1979 Congress initiated, and in 1981 and 1984, renewed, two solemn promises to tens of thousands [2] of sick Vietnam veterans. In the Veterans' Health Programs

[2] For precise numbers over time, see Reasons for Granting the Petition, p. 13, *infra*.

Extension and Improvement Act of 1979, Pub. L. No. 96-151, § 307, 93 Stat. 1092, 38 U.S.C.A. § 527 note (1991) (as amended) (the Act) Congress mandated: first, that the Government would conduct an epidemiological study of whether any of the cancers and other diseases Vietnam veterans suffered were borne disproportionately by those who were more likely to have been exposed to Agent Orange [3] or other defoliant herbicides containing dioxin which the Government had sprayed in Vietnam; and second, that the Government would pay disability compensation to Vietnam veterans for, and death benefits to their families for any veterans' deaths resulting from, any diseases found to be associated with such exposures. This case challenges the Government's breach of those solemn commitments.

Instead of conducting the mandated epidemiological study, in 1988, the then Administrator of Veterans Affairs (now the Secretary)[4] cancelled it. He did so before ever collecting, from physical examinations and health histories of the study subjects, Jt. App. 109F-114,[5] any information on adverse health effects. Because of the cancellation, hundreds of thousands of Vietnam veterans have been prevented from learning whether diseases they have suffered, and, for many, died from, were associated with likely exposure to the herbicides' toxic chemical dioxin.[6] And they, and their families, have been deprived

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[3] Agent Orange was the principal herbicide sprayed in Vietnam and accounted for virtually all of the herbicide sprayed containing dioxin. *Veterans and Agent Orange: Health Effects of Herbicides Used in Vietnam,* Institute of Medicine, National Academy of Sciences, 27, 87, 91 (National Academy Press, 1994) (NAS Report).

[4] See App. 2a, n.1.

[5] All citations to "Jt. App. ——" refer to the Joint Appendix filed in the proceedings before the United States Court of Appeals for the District of Columbia Circuit.

[6] Dioxin is a highly toxic chemical, 2, 3, 7, 8-tetrachlorodibenzo-p-dioxin (TCDD), produced as an unintended by-product in manufacturing Agent Orange and other herbicides which together accounted for about 60% of the herbicides sprayed in Vietnam. See NAS Report at 27, 89, 97-98.

of VA disability and/or death compensation which would have been provided if the study had revealed such results.

Petitioners (the veterans) know those losses intimately. The American Legion, a congressionally-chartered, non-profit, veterans service organization has approximately 3 million members, including about 1 million Vietnam-era veterans. Many of these Legion members were exposed to herbicides containing dioxin during the Vietnam War. They believe the cancers and other serious diseases they have contracted are due to that exposure. They have sought service-connected disability compensation from the Department of Veterans Affairs (VA) but have been denied because of inadequate scientific evidence linking their adverse health effects with exposure.

Individual petitioners Julio Gonzalez and Bill Atwell are Vietnam veterans who developed serious diseases, including bladder cancer and kidney cancer, respectively, after exposure to phenoxy herbicides, *i.e.*, herbicides containing dioxin, in Vietnam. Petitioner Paul L. Sutton is a former Marine who served two tours in Vietnam and, after exposure to phenoxy herbicides in Vietnam, fathered three children with severe birth defects. Petitioners Marel J. Macki, Beverly Nehmer and Carol Delaney-Ridolfi are the surviving spouses of Vietnam veterans who died from malignant melanoma and brain cancer, leukemia, and acute myoblastic leukemia, respectively, after exposure to phenoxy herbicides in Vietnam.

B. The Statutory Mandate And Permissible Misclassification

Pub. L. 96-151 grew from Congress' recognition in the late 1970's that a large number of Vietnam veterans, people in their 20's and 30's, who believed they had been exposed to Agent Orange, were beginning to contract cancers and other serious diseases, as well as produce children with birth defects. The law was enacted within five weeks after the Comptroller General published a report that sufficient military records of ground troops and

herbicide spray location existed to estimate which ground units were most likely to have been exposed to Agent Orange. The Comptroller recommended that Congress direct various government agencies to determine whether a study was needed of "the health effects of herbicide orange on ground troops." [7]

Originally, in 1979, Congress required VA to "conduct an epidemiological study [8] of [veterans] who *were exposed* to dioxins. . . .", Pub. L. 96-151, § 307(a)(1) (Emphasis added) Congress thereby implied its belief that the military records were, in general, sufficiently detailed to determine which individual veterans had actually been exposed. But, by 1981, Congress recognized that this premise was false, and that its statutory restriction of study subjects to veterans who "were exposed" had prevented starting the study of adverse health effects. S. Rep. 89, 97th Cong., 1st Sess. 25-26 (May 15, 1981) (accompanying S. 921, the basis for Pub. L. 97-72, 95 Stat. 1061 (Nov. 3, 1981)). Thus, in 1981, to enable the health study to proceed, *id.*, Congress repealed the restrictive "were exposed" requirement. Instead, Congress substituted the more permissive requirement that VA need study merely health effects which "*may result from exposure. . . .*" (Emphasis added) Pub. L. 97-72, § 401, 95 Stat. 1061 (Nov. 3, 1981).

In January 1983, VA contracted with the federal government's Centers for Disease Control (CDC) to develop

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[7] "U.S. Ground Troops In South Vietnam Were In Areas Sprayed With Herbicide Orange", Report by the Comptroller General of the United States, at 9 (Nov. 16, 1979). Petitioners believe that this report is admissible as containing important background and technical information, *see Esch v. Yeutter*, 876 F.2d 976, 991-992 (D.C. Cir. 1989), and a copy is lodged with the Clerk's Office.

[8] "Epidemiologists study the effects of various phenomena on humans under uncontrolled or 'natural' conditions. These effects are correlated with other observed facts in an attempt to develop significant relationships among the data. The science is limited, however, in that inferences may be drawn, but relationships cannot be proved by the correlations alone." *Ethyl Corp. v. Environmental Protection Agency*, 541 F.2d 1, 42 (D.C. Cir. 1976).

a "protocol" (design) for, and conduct, the study. Jt. App. 162. From the outset, CDC recognized that because the military records generally could not identify which individual veterans definitely had or had not been exposed, it would instead have to distinguish between groups of veterans based on the groups' respective likelihoods of exposure. See Jt. App. 102-103, 114C. For the same reason, CDC acknowledged that there was a risk of "misclassification," *i.e.*, some individual veterans who had not, in fact, been exposed might be included in the "likely exposed" cohort (group), and others who actually had been exposed might be in the "likely not exposed" cohort. See Jt. App. 103, 107, 114B-C, 114L.

In the science of epidemiology there are ways to protect against and counteract measurement error from misclassification. Jt. App. 303-305. Indeed, CDC designed the study with this in mind to include not only two cohorts, one "likely exposed" and one "likely not exposed," both from a sector of Vietnam which had heavy spraying in it, but also a third cohort from another sector "where there is good evidence of little or no herbicide usage." Jt. App. 103, 107.

Moreover, CDC recognized that in epidemiology random misclassification does not *per se* render a study scientifically invalid, even if the actual misclassification is "sizeable." Jt. App. 114C, 195-96. What such misclassification does is to make it harder to detect the real increased risks of adverse health effects from exposure, and thereby to underestimate whether, and, if so, to what extent, certain diseases correlated with exposure. Jt. App. 114B-114C, 195-96. As CDC noted with respect to this study, notwithstanding random misclassification, "[i]f health effects are strong enough, they would be discovered in the study, albeit underestimated." Jt. App. 196.

CDC did not believe that its study needed to, nor could, confidently identify cohorts whose differences in exposure were " 'meaningful' [in the sense that they] might a priori

be considered enough to result in differences in long-term health. . . ." Jt. App. 194. CDC's goals for the study were modest: "CDC believes only that its sampling plan should identify groups of men who will differ to some degree in their accumulated exposure." *Id.*

In July 1983, the Office of Technology Assessment (OTA), which Congress had charged to review the study protocol for "scientific validity and objectivity", Pub. L. 96-151, § 307(a)(2)(A)(i), (B)(i) (1979), 38 U.S.C.A. § 507 note § (a)(2)(A)(i), (B)(i), and approve it before the study could be begun, *id.*, approved CDC's protocol.[9] VA (through CDC) was statutorily obligated to carry out the study according to the approved protocol, Pub. L. 96-151, § 307(a)(2)(A)(ii)(C) (1979), 38 U.S.C.A. § 527 note § (a)(2)(A)(ii) (C). The Secretary was not authorized to cancel the study until after he had submitted to Congress his "first" report, Pub. L. 97-72, § 401(a)(2) (Nov. 3, 1981), 38 U.S.C.A. § 527 note § (a)(3), describing the "results thus far obtained under the study." Pub. L. 96-151, § 307(b)(2), 38 U.S.C.A. § 527 note § (b)(2).

Congress contemplated that those results would enable it to determine whether to continue to authorize VA hospital and nursing home care for Vietnam veterans who "may have been exposed during . . . service to dioxin", Pub. L. 97-72, § 401(b)(2) ¶ 4 (1981) with Pub. L. 97-72, § 102(a)(1) (2) (1981), as well as implicitly to

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[9] In its approval letter, OTA noted that: "Given the imperative to execute those studies [one of which was the study at issue], the CDC protocols provide an appropriate general construct that it is not likely to be improved upon . . . Congress, in mandating the study, is seeking to provide answers to questions that plague veterans and their families; the available records enable the study to be undertaken but the limited quality of those records (sic) also probably limits the accuracy of the answers that can be expected." Letter from John H. Gibbons to Honorable Harry N. Walters, Administrator, Veterans Administration, July 8, 1983. Petitioners believe that this letter is admissible per footnote 9. The Clerk's Office has a copy.

allow the VA administrator to determine for which diseases he should grant compensation based on presumptive Agent Orange exposure. Pub. L. 97-72, § 401(b)(2) ¶ 3 (1981). In October 1984, Congress amended Pub. L. 96-151 to make explicit that, based on the "results" obtained pursuant to Pub. L. 96-151, § 307(b)(2), the Administrator was to grant service-connected compensation to veterans for any diseases for which the study revealed association with exposure to dioxin. See Pub. L. 98-542, § 8(a) (Oct. 24, 1984) with Pub. L. 98-542, § 5(a)(1)(A), 38 U.S.C.A. § 527 note, § (b)(3).

C. Study Cancellation And The Litigation Below

On February 9, 1988, the Secretary, after receiving several reports and recommendations, decided to cancel the study. He determined that no "scientifically sound study can be undertaken," Jt. App. 262, because, as construed by the Court of Appeals, misclassification made it "impossible to determine whether a particular group of veterans is more likely to have been exposed to Agent Orange and other herbicides than a comparable cohort of their peers." App. 25a. The cancellation decision was based essentially on two conclusions: 1) the risk of misclassification in the military records was so great that it would destroy the scientific validity of the study, see App. 22a-25a, unless the accuracy of the military records in distinguishing between exposed and unexposed veterans could be independently verified, App. 23a-25a and n.16; and 2) no method existed to independently verify the records' accuracy. App. 23a-24a.

In 1990, The American Legion and various individual petitioners filed two separate actions in the United States District Court for the District of Columbia.[10] See App. 24, 27. They sought to require the VA to conduct the cancelled Agent Orange exposure study and grant service-connected disability compensation to Vietnam veterans

[10] The actions were subsequently consolidated in the district court and remained so on appeal. See App. 1a, 30a.

for, and death compensation to their survivors for veterans' deaths resulting from, any diseases which would be warranted by the study's results. The veterans presented several claims that respondents' study cancellation violated Pub. L. 96-151, as amended, and was therefore "not in accordance with law" under the Administrative Procedure Act (APA), 5 U.S.C. § 706(2)(A), as well as several claims that the cancellation was "arbitrary and capricious" under the same section. See generally App. 43a-47a.

The district court denied the Government's motion to dismiss, App. 36a, n.6, tacitly agreed with the veterans that if the White House Domestic Policy Council's cancellation of the study had been the final decision to cancel, it would have been illegal, App. 38a-40a and nn.9-10, and rejected the Government's argument that it was entitled to summary judgment based on Congress' purported ratification by appropriation of the cancellation decision. App. 36a-37a. However, the district court granted the Government summary judgment on the merits. App. 47a.

In the United States Court of Appeals for the District of Columbia Circuit, the veterans raised two issues relevant to this petition.[11] First, they argued that the Act's purpose, language and structure, as well as the language of the closely related 1983 radiation exposure study statute, Pub. L. 98-160, § 601, 87 Stat. 1006, 38 U.S.C.A. § 527 second note (1991) (as amended), revealed that Congress clearly intended that the "results" the Secretary had to report before he could cancel the study were health results, not merely progress. Since the Secretary indisputably cancelled the study before gathering any health results, the cancellation was contrary to law.

The D.C. Circuit rejected this argument. Instead, the Court of Appeals held that it was not clear whether Congress intended to require the Secretary to report health

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[11] Petitioners are not pursuing in this Court their argument that the Secretary applied the repealed "were exposed" standard of the 1979 statute. See App. 18a-22a.

effects or merely "progress" before he could cancel the study. App. 13a-17a. Therefore, under *Chevron U.S.A., Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 841-42 (1984), the Circuit held it "must defer to the Secretary's interpretation" that he only needed to submit a progress report to Congress prior to cancellation, since the court believed that the Secretary's interpretation was permissible. App. 14a.

But in so ruling the Court of Appeals wholly failed to consider, let alone apply, this Court's longstanding principle that ambiguous language in statutes for the benefit of veterans must be construed favorably to the veterans. In *Brown v. Gardner*, 115 S. Ct. 552, 555 (1994), this Court most recently noted the "rule that interpretative doubt is to be resolved in the veteran's favor . . . ."; *accord, e.g. King v. St. Vincent's Hospital*, 502 U.S. 215, 220 n.9 (1991).

The Court of Appeals held, in effect, alternatively, that even if the veterans were correct that the "traditional tools of statutory construction" showed Congress clearly intended "results" to be health effects, that construction must be rejected here because it would lead to the purportedly "absurd results" that the Secretary would have to conduct a study he had determined could not be scientifically valid. App. 14a, 17a, n.13, 17a-18a. The appeals court recognized, however, that reading the Act to require the Secretary to conduct the study would only be "absurd" if it were "[a]ssum[ed]" that the Secretary's conclusion that it was impossible to do a scientifically valid study was "accura[te]." App. 18a.

The veterans' second issue challenged not just the "accuracy" of the Secretary's conclusion that it was impossible to do a "valid" study with military records without independent verification, but its fundamental "rationality." Petitioners did not dispute that *if* the Secretary had rationally concluded that military records alone could not produce a valid study unless their accuracy were independently verified, then the veterans' claims would fail because

independent verification was not available.[12] Rather, petitioners argued that the Secretary's threshold determination that military records were not adequate for a scientifically valid study unless their accuracy had been independently verified was itself "arbitrary and capricious." Thus, the Secretary had no rational basis for having refused to do the military records study regardless of his inability independently to have verified their accuracy.

Initially, the veterans argued that the sole basis in the record for the Secretary's conclusion that the risk of misclassification was so great that the military records could not produce a scientifically valid study unless their accuracy was independently verified was the "feelings" of the Science Subpanel. Jt. App. 46. Respondents had presented no scientific principles for judging when misclassification risk becomes so great that it destroys a study's scientific validity. Reliance on scientists' mere conclusory opinion, without any foundation in scientific methodology, the veterans argued, was "arbitrary and capricious". The Appeals Court responded that the Secretary's conclusion that the military records could not generate a valid study unless separately verified rested not only on the Subpanel's "feelings", but also on three opinions or findings from other scientific groups. App. 24a-25a, n.16.

Finally, the veterans argued that the Secretary's conclusion that the risk of misclassification was so great that it prevented the study from being scientifically valid unless the military records' accuracy was independently verified was "arbitrary and capricious" because the Secretary failed to provide any reasoned explanation for why the degree of misclassification risk the Subpanel perceived exceeded the maximum permitted for a study to be

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[12] Thus, the Court of Appeals misconceived the veterans' argument when it asserted that "the question in these appeals is whether the Secretary had a rational basis for determining that no known method existed to verify whether the military records based assessments differentiated between exposed and non-exposed veterans in the way necessary for a cohort study." App. 24a.

scientifically valid. The veterans did not dispute the Subpanel's assessment of the degree of risk of misclassification,[13] *i.e.*, that "[t]he combined effect of these two sources of misclassification is unclear, but undoubtedly they would seriously bias measures of effect toward the null and greatly reduce study power." Jt. App. 46. (That is, misclassification would make it much harder to identify the adverse effects due to herbicide exposure.) Instead, the veterans challenged the fact that neither the Secretary nor the experts on whom he relied explained why that degree of misclassification would destroy the study's validity, rather than merely make it harder for the study to detect true adverse effects from exposure. The Court of Appeals never addressed this argument.

REASONS FOR GRANTING THE PETITION

The number of people injured by the Secretary's challenged decision to cancel the Agent Orange exposure study is huge. In 1978-1980 alone, 33,156[14] Vietnam veterans expressed concern to VA that their exposure to herbicides in Vietnam may be causing them adverse health effects, and were accordingly given VA's Agent Orange health examination and listed on VA's Agent Orange Registry. Many of the diseases which the veterans suffered were cancers which are believed to have a long latency period.[15] Today, as more Vietnam veterans have become sick, the number on the Registry has catapulted to 245,162.

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[13] Accordingly, the appeals court misconceived the veterans' argument when it said that "appellants charge the Secretary should have . . . determine[d] . . . the degree of misclassification. . . ." App. 25a.

[14] This and the succeeding number of individuals on the Agent Orange Registry were provided telephonically to counsel's office by the Environmental Agents Service, VA's Office of Public Health and Environmental Hazards (Aug. 1-4, 1995).

[15] NAS Report at 435.

Moreover, the number of people harmed by the VA's refusal to conduct the study is not only the veterans themselves, but also their families, each of whom is potentially being deprived of thousands of dollars per year of VA disability compensation which their veteran predictably would have been receiving if the study had found the veteran's disease associated with herbicide exposure.[16] Perhaps most tragically, when a veteran dies prematurely of diseases which may have been due to Agent Orange exposure, the spouse and children are being deprived of death benefits to which they otherwise might have been entitled.

Against the possibility that tens or hundreds of thousands of veterans and their families might benefit from having the statutorily mandated study conducted, the only justification the Secretary has offered for refusing to do the study boils down to his concern that misclassification will "seriously bias measures of effect toward the null and greatly reduce study power". Jt. App. 46. Taking the Secretary's concern to its logical limit, the misclassification might be so serious that the study would not be able to identify any adverse health effects associated with herbicide exposure, even if in fact such associations exist. Jt. App. 287.

But whether the study would in fact fail to find any associations between exposure and any diseases cannot be known in advance. The mere possibility that it might turn out to be unproductive pales in comparison to the possibility it might succeed in identifying diseases associated with Agent Orange. As CDC said, if the associations are strong enough, they will be detected even if there is a high degree of random misclassification. Jt. App. 196.

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[16] Conservatively, multiplying the number of veterans on the Registry by 2.5 (less than the 2.63 average number of persons per American household as of March 1993 reported by the Census Bureau), the maximum number of individuals potentially injured may be estimated at 612,905.

While other epidemiological studies have been done of Vietnam veterans based solely on service in Vietnam,[17] and a small scale Agent Orange exposure study has been done of veterans associated with spraying the herbicides from fixed wing aircraft [18], none has served the essential and unique function which the cancelled Agent Orange exposure study was to serve: to assess the adverse health effects of likely exposure to herbicides on the vast majority of Vietnam veterans who were exposed to herbicides—the ground combat troops. This is the missing, central piece of the puzzle. Without it, there would never be any direct information as to what, if any, health effects were associated with exposures experienced by the ground forces who fought in the jungles and other heavily vegetated areas where the herbicides were sprayed.

This is a nationwide suit. It challenges a single agency action that has had nationwide effect. It is brought by a national veterans service organization including approximately 1 million Vietnam veterans throughout the country, which serves all veterans who request assistance. While there is no conflict in the circuits, as a practical matter this case is similar to a nationwide class action in which there would never be a conflict. Here, because of the nationwide character of the suit, and the time and expense of pursuing it, unless this Court grants certiorari now, it predictably would never have another chance to consider these issues based on a conflict in the circuits, because it is virtually inconceivable that any other suit to enforce Pub. L. 96-151 would ever be brought.[19]

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[17] See Vietnam Experience Study, Jt. App. 104; NAS Report at 389-391 and Selected Cancer Study, Jt. App. 104-5; NAS Report at 391-393.

[18] See "Ranch Hand" Study, NAS Report at 385-386.

[19] As with important decisions of nationwide effect from the United States Court of Appeals for the Federal Circuit, notwithstanding the absence of a conflict in the circuits, the decision of the D.C. Circuit below raises "a matter of special importance to the entire Nation." *Cardinal Chemical Co. v. Morton International,*

In the legislative history to the Agent Orange Act of 1991, Pub. L. 102-4 (Feb. 6, 1991), 105 Stat. 11, 38 U.S.C. § 1116 (1993), Congress itself recognized that this suit was pending challenging the cancellation of the study mandated by Pub. L. 96-151 and that that law remained in effect.[20] Only if the Act is enforced to require the VA to conduct the study will the hundreds of thousands of affected Vietnam veterans and their surviving spouses be given the chance Congress intended that it might produce the evidence needed to entitle them to VA disability and death compensation.

I. THE COURT OF APPEALS DISREGARDED THE PLAIN LANGUAGE, PURPOSE, AND STRUCTURE OF THE VETERANS' HEALTH PROGRAMS EXTENSION AND IMPROVEMENT ACT OF 1979, AS WELL AS THE PLAIN LANGUAGE OF A CLOSELY RELATED STATUTE, WHICH REQUIRE THE SECRETARY TO REPORT INITIAL HEALTH RESULTS BEFORE BEING ALLOWED TO CANCEL THE STUDY

It is conceded that the Act's language does not authorize the Secretary to cancel the study until "after the submission [to Congress] of the first report," 38 U.S.C.A. § 527 note § (a)(3), which describes "the results thus far obtained under the study." 38 U.S.C.A. § 527 note § (b)(2). Petitioners contend that the Act's language, purpose and structure, reinforced by the language of the closely related radiation exposure study statute, reveal that Congress clearly intended that the initial study "results" the Secretary had to report before he could cancel

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Inc., 113 S. Ct. 1967, 1971 (1993). Indeed, this Court has very recently recognized the appropriateness, absent circuit conflict, of granting review of cases involving important interests of veterans, *Gardner*, 115 S. Ct. 552, and Agent Orange. *Hercules Inc. v. The United States*, 24 F.3d 188 (Fed. Cir. 1994), *cert. granted*, 63 U.S.L.W. 3717 (April 3, 1995).

[20] Cong. Rec. S. 1270 (Jan. 30, 1991) (colloquy between Senator DeConcini and Senator Daschle); Cong. Rec. H. 730 (Jan. 29, 1991) (Statement of Representative Evans).

were results as to adverse health effects. The Court of Appeals, in straining to avoid this obvious conclusion by finding that Congress equally could have intended to require only a "progress" report, disregarded basic principles of statutory construction.

Although this Court has recognized that "[t]he starting point in interpreting a statute is its language," *Good Samaritan Hosp. v. Shalala,* 113 S. Ct. 2151, 2157 (1993), and the place to begin assessing the ordinary meaning of statutory language is the "dictionary," *e.g., MCI Telecommunications Corp. v. American Telephone and Telegraph*, 114 S. Ct. 2223, 2229 (1994); *Smith v. United States*, 113 S. Ct. 2050, 2054 (1993), the Court of Appeals avoided dictionaries. Instead, it relied solely on "common parlance" to conclude that " 'results' is . . . subject to multiple meanings." App. 14a. But this is too facile.

The dictionary definitions of "results" and "progress" are significantly different. "Result" denotes the final product or conclusion of a process, whereas "progress" signifies merely moving forward toward an end. "Result" is defined as: "that which results; the outcome, consequence or effect", *The American College Dictionary,* Random House, 1035 (1964); "the conclusion or end to which any course or condition of thing leads, or which is obtained by any process or operation." Black's Law Dictionary, 1478 (4th ed. 1957). By contrast, "progress" is defined as: "forward or onward movement in space or course"; *The American College Dictionary,* Random House, 967 (1964); "movement toward a goal." The American Heritage Dictionary, 2nd College Ed., Houghton Mifflin 990 (1985). To construe "results", the end of a process, as intended to mean merely interim steps taken in a process, is to rip "results" from its mooring. *See Bethesda Hospital Association v. Bowen*, 485 U.S. 399, 404 (1988).

While this Court has repeatedly emphasized that courts must interpret a statute in light of its "object and policy,"

United States National Bank of Oregon v. Independent Insurance Agents of America, Inc., 113 S. Ct. 2173, 2182 (1993), quoting *United States v. Heirs of Boisdore*, 49 U.S. (8 How.) 113, 122 (1849), its "purpose", *Federal Trade Commission v. Anheuser-Bush, Inc.*, 363 U.S. 536, 546 (1960), the Court of Appeals here failed to address the Act's purpose, or how it bore on the intended meaning of "results." The answer is manifest both on the face of the statute and in its legislative history.

The legislative history shows that the Act was a response to the facts that: the public recognized that dioxin contained in Agent Orange and other herbicides sprayed in Vietnam was a highly toxic substance, 125 Cong. Rec. 15180 (June 18, 1979) (Statement of Sen. Javits), 125 Cong. Rec. 15178-79 (June 18, 1979) (Statement of Sen. Cranston); significant numbers of Vietnam veterans were seeking VA service-connected disability compensation for cancers and other serious diseases they believed were associated with exposure to dioxin in Vietnam, but VA was denying all the claims except for one skin condition, chloracne, 125 Cong. Rec. 15179 (June 18, 1979) (Statement of Sen. Cranston); no large scale epidemiologic studies had been done to enable the government to distinguish which diseases may have been due to dioxin exposure from those which were probably not, 125 Cong. Rec. 15179 (June 18, 1979) (Statement of Sen. Cranston), 125 Cong. Rec. 15180 (June 18, 1979) (Statement of Sen. Javits); and the "VA ha[d] shown an inexcusable lack of priority for this study." 125 Cong. Rec. 15180 (June 18, 1979) (Sen. Cranston).

The Act's purpose was to ensure that the Government, by conducting an epidemiological study, would learn whether Vietnam veterans who had a greater likelihood of having been exposed to phenoxy herbicides had a higher incidence of certain diseases, 38 U.S.C.A. § 527 note, § (a)(1)(A), so that if so, VA could grant presumptive service-connected disability and death compensation for such diseases, 38 U.S.C.A. § 527 note,

§ (b)(3), and Congress could continue to authorize VA hospital and nursing home care to treat them. 38 U.S.C.A. § 527 note, § (b)(4).

How the statutory purpose bore on what Congress intended by requiring an initial report of "results" before the study could be canceled is readily apparent: the only way Congress' purposes could be achieved was if VA reported to it health results before it cancelled the study. Indeed, the Court of Appeals concedes that Congress never even considered the possibility that the study might be cancelled before it "yield[ed] substantive health results." App. 17a, n.13. Just as in *Anheuser-Bush, Inc.*, 363 U.S. at 546, "the incompatibility of the Circuit Court's [construction] with the purpose of [the Act]" is fatal.

And the Court of Appeals' analyses of structure are similarly flawed. That Congress required "update" reports for protocol approval, § (a)(2)(B)(ii), prior to conducting the study, whereas it specified "results" reports for the study itself, § (a)(3), (b)(2), App. 16a, in no way undermines the principle that Congress' use of different words implies it intended different meanings. *See Immigration and Naturalization Serv. v. Cardoza- Fonseca*, 480 U.S. 421, 432 (1987), quoting *Russello v. United States*, 464 U.S. 16, 23 (1983), (" 'where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.' ") Had Congress intended to require that VA need only make an "update" report before cancellation, it would have said so.

Nor does the Court of Appeals face the fact that by reading the Act as if Congress had written that the Secretary could cancel the study after one "progress" report, rather than one report of "results", it has effectively nullified the difference between the restrictive cancellation scheme in the Act and the far more permissive cancellation scheme in the analogous radiation exposure study

law, the Veterans Health Care Amendments of 1983, Pub. L. 98-160, § 601, 97 Stat. 1006-08 (1983), 38 U.S.C. § 527 second note (as amended). App. 16a-17a. *See Gardner*, 115 S. Ct. at 555 (Court analyzes analogous statutes as one of its tools of statutory construction). The radiation statute, unlike Pub. L. 95-151, does not require OTA approval of VA's protocol as a prerequisite to conducting the study, nor VA implementation in compliance with an approved protocol. Moreover, it expressly authorizes Secretarial cancellation of the radiation study at any time the Secretary determines, after consulting OTA, that it cannot be done in a scientifically valid manner, and the Secretary so notifies Congress. 38 U.S.C. § 527 second note § (a)(1)(B), (C).

Since, as a practical matter, the mere requirement to submit a "progress" report as a prerequisite to cancellation in no way constrains the Secretary's discretion as to when to cancel, the Circuit Court has eviscerated the Agent Orange statute to the point that it confers as much cancellation discretion on the Secretary as the radiation statute, even though the language of Pub. L. 96-151's cancellation scheme is much more restrictive. This is impermissible. *E.g.*, *West Virginia University Hospitals, Inc. v. Casey*, 499 U.S. 83, 99 (1991).[21]

Finally, the Circuit Court's assertion that the fact that the radiation statute requires the Secretary to report to Congress "a description of the *progress on and any re-*

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[21] Indeed, in 1984, Congress itself expressly repudiated the appeals court's view that Pub. L. 96-151 conferred as much discretion on the Secretary to cancel the dioxin study as to cancel the radiation study when Congress noted that Congress "requir[ed] . . . the conduct of thorough epidemiological studies of the health effects experienced by veterans in connection with exposure both to herbicides containing dioxin and (if not determined to be scientifically infeasible) to radiation, ..." Pub. L. 98-542, § 2(4) (Oct. 24, 1984), 98 Stat. 2725. Thus, Congress understood that after OTA protocol approval, the duty to conduct the dioxin study was categorical, whereas the radiation study could be cancelled at any time the Secretary determined invalidity.

sults under such [radiation exposure] study," 38 U.S.C.A. § 527 second note, § (a)(5)(A) is not "inconsistent" with construing "results" in the Act to mean "progress" report, App. 17a, is indefensible. (Emphasis added) It is fundamental that all words in a statute are to be construed to have a separate meaning so that none is rendered superfluous. 2A Sutherland's Statutory Construction § 46.06 (5th ed. 1991). Congress knew exactly the difference between requiring a report of a study's "progress" and its "results." Neither word is superfluous and they are not equivalent. The Court of Appeals' holding that the congressionally intended meaning of "results" was "ambiguous", and therefore necessitated proceeding to *Chevron*'s step two, is unwarranted.

II. FOR RESOLVING AMBIGUITIES IN STATUTES BENEFITTING VETERANS, THE *CHEVRON* RULE REQUIRING DEFERENCE TO AN AGENCY'S REASONABLE INTERPRETATION, ON WHICH THE COURT OF APPEALS RELIED, CONFLICTS WITH THE RULE OF *BROWN v. GARDNER* THAT "INTERPRETIVE DOUBT IS TO BE RESOLVED IN THE VETERAN'S FAVOR"

This case presents a sharp conflict between two of this Court's rules of statutory construction. By invoking the rule of *Chevron* deference, the Court of Appeals wholly disregarded this Court's more narrow rule, most recently announced in *Gardner*, that for ambiguities in veterans benefits statutes, "interpretive doubt is to be resolved in the veteran's favor." 115 S. Ct. at 555. That rule grows out of the special debt the nation has to those who have sacrificed to protect her, and originated at least as far back as *Boone v. Lightner*, 319 U.S. 561, 575 (1943) and *Fishgold v. Sullivan Drydock & Repair Corp.*, 328 U.S. 275, 285 (1946). This rule has been endorsed more recently not only in *Gardner*, but in *Coffy v. Republic Steel Corp.*, 447 U.S. 191, 196 (1980) and *St. Vincent's Hospital*, 502 U.S. at 221 n.9.

Since the Veteran's Health Programs Extension and Improvement Act of 1979 at issue here was enacted to

benefit veterans, it is the type of statute to which the *Gardner* rule applies. Veterans could only gain VA compensation from the Act if the study is performed at least to the stage of gathering initial health results. Thus, for "interpretive doubt . . . to [be] resolved in the veteran's favor" would require construing "results" as health results, so that the cancellation would have been illegal and the study would have to be done. This is, of course, the exact opposite of what would have been required under *Chevron*, assuming that respondents' interpretation was permissible. On the facts of this case, therefore, the two canons of construction are in irreconcilable conflict.

The *Gardner* canon of construction might operate at step one of *Chevron*, so that potential ambiguity would be eliminated before ever reaching step two. This would be similar to *Gardner*'s reliance on the canons that "a given term is used to mean the same thing throughout a statute," 115 S. Ct. at 555, and that "it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion [of particular language]", *id.*, at 556, to support its *Chevron* step one conclusion that "the text and reasonable inferences from it give a clear answer against the Government, ..." *Id.* Accord, *Dole v. United Steelworkers of Am.*, 494 U.S. 26, 36, 42-43 and n.10 (1990); *Cardoza-Fonseca*, 480 U.S. at 442-443, 446-450.

Or, the *Gardner* canon might operate to supercede *Chevron* deference at *Chevron*'s step two, as in *DeBartolo Corp. v. Florida Gulf Coast Building and Construction Trades Council*, 485 U.S. 568, 574-578 (1988). As between substantive statutes themselves, the more narrow rule of construction, here the *Gardner* rule, should supercede the more general. *See Traynor v. Turnage*, 485 U.S. 535, 547-48 (1988). Only this Court is in the position to resolve the conflict in this case between these two canons of construction, and thereby clarify the law for all veterans nationwide on this important matter.[22]

[22] The Court of Appeals' alternative ground for rejecting the veterans' statutory argument, that it would lead to "absurd re-

III. UNDER THE ADMINISTRATIVE PROCEDURE ACT, AN AGENCY DECISION BASED SOLELY ON FACTS AND SCIENTISTS' CONCLUSORY OPINIONS, BUT FAILING TO CONSIDER RELEVANT SCIENTIFIC PRINCIPLES AND EXPLAIN REASONING FROM THE FACTS FOUND TO THE OPINION REACHED, IS "ARBITRARY AND CAPRICIOUS" UNDER *BURLINGTON TRUCK LINES* AND *BALTIMORE GAS*

For an agency's scientific determination to avoid being "arbitrary and capricious" under the APA, it must be based on more than facts and conclusory expert opinions; it must also have considered the relevant scientific principles and explained how the agency reasoned from the facts found to the conclusion reached. These requirements flow directly from this Court's decisions. *In Baltimore Gas*, 462 U.S. at 105-106, the Court recognized that the usual criteria that govern analysis under the "arbitrary and capricious" clause of 5 U.S.C. § 706(2)(A) also govern review of scientific decision-making.

A. Failure To Consider Relevant Factors

Thus, the Court "is to determine whether the [agency] has considered the relevant factors. . . ." *Baltimore Gas*, 462 U.S. at 105; accord, *Motor Vehicles Manufacturers*, 463 at 43 (agency may not "fail[] to consider an important aspect of the problem, ..."). What are the

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sults", App. 14, 17a, n.13, and 17a-18a, hinges entirely on the court's "[*a*]*ssuming the accuracy* of the Secretary's conclusion that a scientifically valid Agent Orange study was infeasible. . . ." (Emphasis added) App. 18a. Thus, even the Court of Appeals seems to concede that unless the Secretary's conclusion that it was impossible to conduct a scientifically valid study were "accurate" (or at least had a rational basis), there would be no logical ground for finding it "absurd" to read the Act as requiring the study.

The veterans' last reason for granting the petition shows that the Secretary had no rational, or lawful, basis for his conclusion that it was impossible to do a valid study. Accordingly, the Court of Appeals' finding of "absurd results" was unfounded, and the study cancellation not only violated the Act, but was also illegally "arbitrary and capricious."

"relevant factors" must necessarily be determined by reference to the particular decision being challenged.

Here, the decision is the Secretary's conclusion that the degree of risk of misclassification makes it impossible to do a scientifically valid epidemiological study with military records alone, unless their accuracy is independently verified. Given the nature of this decision, it would be essential for the Secretary (or his scientists) to have considered both what was the degree of risk of misclassification to which the study was subject, and what are the scientific principles [23] for determining when risk of misclassification becomes so great that it not only makes it harder to detect true adverse health effects, but renders the study scientifically invalid.

The first element is not in dispute because the Subpanel made findings as to the degree of risk of misclassification that a military records study would present. First, it identified the two principal problems with the military records which prevented their being able to verify which individuals had been exposed to herbicides containing dioxin and which had not: (i) unit dispersion—the pilot study on which the subpanel relied showed that "[o]n a substantial number of days," some soldiers in combat units eligible for the study were dispersed for some time period from the main unit, but the military records failed to report which individuals within the unit were located where; [24] and (ii) incomplete spray records—although

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[23] In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S. Ct. 2786, 2797 (1993), this Court recognized that it was so important that scientists disclose the scientific principles which underlay their opinions that it established that "[t]he focus [of admissibility determinations under Fed. R. Evid. 702] must be solely on [scientific] principles and methodology, not on the conclusions they generate." Similarly, F.R. Civ. P. 26(a)(2)(B), as amended in 1993, generally requires disclosure to other parties before trial not only of "all opinions" to which any retained experts will testify, but also "the basis and reasons therefor."

[24] The main units that the pilot study analyzed were companies, each with approximately 225 soldiers. See Declaration of Richard Christian, ¶ 11, p. 6, ¶ 16, p. 11, ¶ 19-26, pp. 13-19. The military

Ranch Hand spray missions (from fixed wing aircraft) and some perimeter spray missions were recorded, "an unknown, but apparently large proportion of firebase perimeter spray operations were never recorded." [25] Jt. App. 45. The Subpanel observed that these problems would inevitably cause some study subjects to be misclassified as to exposure status. Jt. App. 45A.

Then, the Subpanel found the degree of risk posed by these two problems to be as follows: "it appears that considerable misclassification of the individual's exposure status is possible; *i.e.*, we found no way, based on military records, to verify an individual's exposure to herbicide or dioxin." App. 45. "The combined effect of [the] two sources of misclassification is unclear . . . undoubtedly they would seriously bias measures of effect toward the null and greatly reduce study power." App. 46. (That is, the misclassification would seriously bias the study toward not detecting true adverse health effects and would reduce its ability to find such effects.)

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records contained information as to the daily location and size of every subunit that was dispersed from the company headquarters, "no matter how small." See Christian Declaration ¶¶ 24-26, pp. 17-19. Thus, for every company the pilot study reviewed, the Subpanel could have determined the size of the subunit (e.g., squad: 4 or 5 soldiers, or platoon: 40 soldiers) that was dispersed from the company headquarters, and therefore whether the potential misclassification affected a large portion of veterans or only a very small proportion. However, the record shows that the Subpanel totally failed to consider this vital factor bearing on the relative severity of the misclassification risk and therefore the scientific validity of the study. Petitioners believe that the Christian Declaration is admissible per footnote 9. The Clerk's Office has a copy.

[25] The military estimated that 98% of all Agent Orange sprayed in Vietnam was sprayed by the Ranch Hand fixed wing aircraft, for which there were complete records of spray location, date and quantity, and only 2% was devoted to perimeter spraying. NAS Report at 90, 94 and 97. Two systems of computerized tapes together were able to account for approximately 19.2 million gallons of the estimated total 20 million gallons of herbicides sprayed in Vietnam. NAS Report 97-98.

As to the second element, however, neither the Secretary nor any experts on whom he relied, explained any scientific principles that they may have used to determine that the degree of misclassification risk the Subpanel found was so high that it exceeded the maximum risk permitted for a study to be scientifically valid. They neither discussed the five factors for making this assessment identified by a senior, full professor of epidemiology at Columbia University's School of Public Health,[26] nor proffered any other scientific standards for making this critical determination.

Instead, the Subpanel relied solely on its "feelings" for its conclusion that the risk of misclassification was so great that it was impossible to do a scientifically valid study with military records, unless their accuracy were independently verified. Its entire justification consisted of the following: "*the Subpanel felt that an additional method to verify exposure is required prior to the conduct of a scientifically valid epidemiological study.*" (Emphasis added) Jt. App. 46.

The Court of Appeals found that the Secretary's "conclusion that an exposure verification method was necessary" was based not only on the Subpanel's "feelings", but also on three specific opinions and findings by other scientists. App. 2a4-25a, n.16. However, the record does not support the appeals court's findings.

First, the Court of Appeals said that "OTA had similarly concluded that because of misclassification problems, an independent method of exposure assessment or some means of verifying the records-based exposure estimates was needed." App. 24a-25a, n.16. In fact, the administrative record shows that OTA *never* endorsed

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[26] Dr. Zena A. Stein had explained in her affidavit that for such a study to be valid, it would need to "meet a minimum threshold of probability and comparability as to . . . five conditions." Jt. App. 302-303. These were summarized by the Court of Appeals as involving "the fact of exposure, amount and duration of exposure, and other personal characteristics and influences that might affect individuals' health." App. 26a.

the Subpanel's opinion as to the unreliability of military records.[27] Rather, OTA favored independent study of blood dioxin levels for the entirely different purpose of verifying whether, as the military records suggested, even the "likely exposed" cohorts had not been heavily exposed to herbicides. Jt. App. 70. OTA ultimately opposed conducting the study not because of any concern over misclassification but because it believed a study would not be useful where "a large percentage of ground troops were [not] heavily exposed to Agent Orange." Jt. App. 78.

Second, the Circuit Court said that "the TCDD study . . . confirmed that military records did not give reliable estimates of exposure to Agent Orange among ground troops." App. 24a-25a, n.16. But the record reveals that the blood study merely failed to verify that the military records were accurate in distinguishing "likely exposed" from "likely not exposed" cohorts. Jt. App. 288a-289. It never found the converse: that the military records were unreliable. Indeed, the court's conclusion is undermined by its own admission of "[t]he fact that the TCDD study left open the possibility that military records might accurately identify exposed veterans at low levels of exposure." App. 24a.

Third, the Court of Appeals asserted that the blood study "confirmed . . . that most ground troops had never faced meaningful exposure to Agent Orange or other herbicides." App. 24a-25a, n.16. In fact, the CDC blood study found that most Army ground troops had not had

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[27] To the contrary, OTA's opinion was that the TCDD study (the blood study) "strongly validate[d]" the military records' accuracy in that it confirmed the military records' showing that the vast majority of ground combat veterans had not been heavily exposed to herbicides. Jt. App. 71. OTA's view was that: "*It remains possible that military records do allow a valid estimate of exposure*, but that the range of exposure in this population is too small to permit evaluation [by the blood study due to removal of dioxin from the body over the 20 years since exposure.]" (Emphasis added) *Id.*

"heavy exposure", but never addressed whether the amount received was "meaningful." Jt. App. 288A-289.[28] Moreover, even if the blood study had found that most troops had not had "meaningful" exposure, that would not have supported the Subpanel's conclusion that misclassification was so great that the military records could not be relied on to distinguish cohorts who had been relatively more exposed from those relatively less exposed. As OTA averred, the military records might be reliable, but the overall level of exposure may have been too low for differences to be detected in the blood 20 years later. See Jt. App. 71-72.

Rather, any opinion as to "meaningfulness" of exposure, at most, would have been a separate potential basis on which the Secretary might have opposed a study on policy grounds as wasteful, but not as scientifically invalid. However, the Secretary never relied on OTA's opinion as to the purported lack of "meaningful" exposure as a basis for canceling the study. If he had, it would have been illegal because Congress in Pub. L. 96-151 did not make its mandate to conduct an exposure study contingent on veterans having been "heavily exposed" to herbicides; instead, it wanted to find out if there were any adverse health effects from whatever level of exposure the veterans had actually experienced.

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[28] While OTA, not CDC, opined that the blood study "confirms a low probability for meaningful exposures for Vietnam veterans as a group", Jt. App. 76, it never cited any scientific evidence in support of its opinion that the levels to which such troops were exposed were not "meaningful." If OTA meant that the levels of exposure to dioxin were too low to cause adverse health effects, that would conflict with CDC's findings that it is not possible "to define objectively 'meaningful' exposure", Jt. App. 102, and that "levels of TCDD in man at which adverse health effects become manifest are not known." Jt. App. 134B. If the Secretary had relied on OTA's opinion in this regard as a ground for canceling the study, there would have been a "genuine issue of material fact" under F.R. Civ. P. 56 as to the "meaningfulness" of the actual exposures, making summary judgment inappropriate.

In short, the Secretary failed to consider the relevant factor of scientific principles, and had no other adequate support for his conclusion that military records alone could not produce a scientifically valid study.[29] His cancellation was "arbitrary and capricious" on this ground alone.

B. Failure To Explain Rational Connection Between Facts Found And Conclusion Reached

In *Burlington Truck Lines*, 371 U.S. at 168, the Court established that for an agency decision to avoid being "arbitrary and capricious" it must also "articulate [a] rational connection between the facts found and the choice made. . . ." Accord, *Baltimore Gas*, 462 U.S. at 105. Here, to the contrary, the Secretary gave no explanation for why he concluded that the misclassification risk would preclude a scientifically valid study, except for the Subpanel's "feelings."

As the Court said in *Burlington*: "There [is] no analysis here to justify the choice made, no indication of the basis on which the [agency] exercised its expert discretion. We are not prepared to and the Administrative Procedure Act will not permit us to accept such adjudicatory practice," 371 U.S. at 167. Likewise as in *Burlington*, the agency here "should have been particularly careful," 371 U.S. at 172, in making its decision because of the serious consequences for Vietnam veterans nationwide from concluding that it was impossible to do a valid study with military records.

To allow this one word—"feelings"—to suffice as an explanation would be to permit " '*expertise* . . . [to] become a monster which rules with no practical limits on its discretion.' " *Burlington Truck Lines*, 371 U.S. at 167, quoting *New York v. United States*, 342 U.S. 882, 884 (1951). (Emphasis in original). This would be a grave

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[29] Indeed, NAS concluded that misclassification risk would *not* make the study scientifically "invalid", but would only be "likely . . . to underestimate the effects if they existed." Jt. App. 287.

injustice to petitioners and hundreds of thousands of Vietnam veterans and their families nationwide. The veterans ask this Court to no more allow unexplained and unreasoned decision-making on matters of national import to go unchecked here than it did in *Burlington* and *Motor Vehicles*, 463 U.S. at 56-57. Too much is at stake for too many veterans.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX A

UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued February 2, 1995 Decided April 25, 1995

No. 93-5404

THE AMERICAN LEGION,

Appellant

v.

EDWARD DERWINSKI, SECRETARY, DEPARTMENT OF VETERANS AFFAIRS; DONNA E. SHALALA, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES; WILLIAM L. ROPER, M.D., DIRECTOR, CENTERS FOR DISEASE CONTROL; VERNON N. HOUK, DIRECTOR, CENTER FOR ENVIRONMENTAL HEALTH AND INJURY CONTROL CENTER; UNITED STATES OF AMERICA,

Appellees

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and Consolidated Case No. 94-5013

VIETNAM VETERANS OF AMERICA; HAROLD A. BUTLER; CAROL RIDOLFI-DELANEY; MAREL J. MACKI; BEVERLY NEHMER,

Appellants

v.

EDWARD DERWINSKI, SECRETARY, DEPARTMENT OF VETERANS AFFAIRS; DONNA E. SHALALA, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES;

WILLIAM L. ROPER, M.D., DIRECTOR,
CENTERS FOR DISEASE CONTROL;
VERNON N. HOUK, DIRECTOR, CENTER FOR
ENVIRONMENTAL HEALTH AND
INJURY CONTROL CENTER;
UNITED STATES OF AMERICA,
Appellees

Appeals from the United States District Court
for the District of Columbia
(90cv1808)

Before: EDWARDS, *Chief Judge*; RANDOLPH and ROGERS, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* ROGERS.

ROGERS, *Circuit Judge*: The American Legion and others appeal from the grant of summary judgment rejecting their challenge to the decision of the Secretary of Veterans Affairs to abandon a congressionally mandated epidemiological study of the effects of exposure to dioxin, a by-product of Agent Orange and other herbicides, on Vietnam veterans.[1] The district court ruled that the Secretary had acted within his discretion in abandoning the Agent Orange Study, which the Secretary had commissioned the Centers for Disease Control to design and conduct, after determining that sampling problems made it unlikely that the investigation would yield scien-

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[1] In 1988, Congress redesignated the Veterans Administration as the Department of Veterans Affairs and named the Secretary of Veterans Affairs (previously, the Administrator of Veterans' Affairs) to head the department. Department of Veterans Affairs Act, Pub. L. No. 100-527, 102 Stat. 2635 (1988). We use the current title "Secretary" in this opinion whenever the statute or record refers to the Administrator of Veterans' Affairs.

tifically valid results. *American Legion v. Derwinski*, 827 F. Supp. 805, 812-14 (D.D.C. 1993). Appellants contend that the Secretary erroneously relied on a repealed standard as the basis for abandoning the study and violated the statute by halting the study before submitting a mandated report of health results to Congress; alternatively, they challenge as arbitrary and capricious the Secretary's conclusion that a scientifically valid study was impossible. Finding these contentions unpersuasive, we affirm.

I.

As background to appellants' contentions, we first outline the statute and the Secretary's efforts to implement the statutory directive for an epidemiological study on the effects of exposure to dioxins during the Vietnam conflict.

A. The Statute. In enacting the Veterans' Health Programs Extension and Improvement Act of 1979, Pub. L. No. 96-151, 93 Stat. 1092 (codified as amended at 38 U.S.C. § 219 note (1988)), *reprinted as amended in* 38 U.S.C.A. § 527 note (1991) (the "1979 Act"), Congress sought to determine by means of an epidemiological study the health effects of exposure to Agent Orange and other herbicides on Vietnam veterans.[2] *Id.* § 307; *see also* S. REP. No. 260, 96th Cong., 1st Sess. 36-40 (1979) ("1979 S. REP."), *reprinted in relevant part in* 1979 U.S.C.C.A.N. 1894, 1922-1926. These herbicides, which the United States military used during the Vietnam conflict, contain varying amounts of dioxins—also

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[2] Epidemiology is "a branch of science and medicine [that] uses studies to 'observe the effect of exposure to a single factor upon the incidence of disease in two otherwise identical populations.'" *DeLuca v. Merrell Dow Pharmaceuticals, Inc.*, 911 F.2d 941, 945 (3d Cir. 1990) (quoting Black & Lilienfeld, *Epidemiological Proof in Toxic Tort Litigation*, 52 Fordham L. Rev. 732, 755 (1984)); *see also* Affidavit of Dr. Zena A. Stein, proffered by appellants, at 2.

referred to as TCDD [3]—which studies have suggested can cause harmful health effects in laboratory animals and consequently led to concern about similar effects in humans.[4] Congress sought to determine whether Vietnam veterans had suffered such adverse health effects as a result of their military service and, if so, to compensate them for their injuries. *See* 1979 S. REP. at 38-40.

The 1979 Act directed the Secretary to conduct an epidemiological study pursuant to a protocol approved by the director of the congressional Office of Technology Assessment ("OTA"). 1979 Act § 307(a)(2)(A)(i). The statute also required the director of OTA to oversee the conduct of the study and report its oversight activities to the appropriate congressional committees. *Id.* § 307 (a)(2). Further, as part of the effort to ensure that the study was "sientifically valid and . . . conducted with efficiency and objectivity," the 1979 Act directed the President to coordinate the Secretary's study with any other Federal governmental studies on the effects of dioxins. *Id.* § 307(c). The 1979 Act expressly required, however, that the Secretary continue the study only "for as long after the submission of [his first] report [to Congress on 'the results thus far obtained under the study'] . . . as the [Secretary] may determine reasonable in light of the possibility of developing through such study significant new information on the long-term adverse health effects of exposure to dioxins." *Id.* § 307(a)(3), (b)(2).

The 1979 Act initially called for an epidemiological study of veterans who "were exposed to" dioxins during the Vietnam conflict. *Id.* § 307(a)(1) (amended 1981). From the outset, a major obstacle to completion of the study was the identification of veterans, other than "Ranch Hands" who did the actual spraying, who had

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[3] TCDD stands for 2,3,7,8-Tetrachlorodibenzo-p-Dioxin, a by-product created during the manufacture of certain herbicides.

[4] *See* 1979 S. REP. at 37-39; Health Study Protocol at 4-5.

been exposed to Agent Orange during their service in Vietnam. S. REP. No. 89, 97th Cong., 1st Sess. 25 (1981) ("1981 S. REP."). To adress this problem, Congress amended the statute in 1981 to require a study of veterans' health effects that "may result" from exposure to dioxins. Veterans' Health Care, Training, and Small Business Loan Act of 1981, Pub. L. 97-72 § 401(a)(1), 95 Stat. 1061 (1981) (codified at 38 U.S.C. § 219 note (1988)), *reprinted in* 38 U.S.C.A. § 527 note ("1981 Amendments"). The 1981 Amendments also expanded the scope of the study to examine health effects that may have resulted from other factors in the overall Vietnam experience, "including exposure to other herbicides, chemicals, medications, or environmental hazards or conditions." *Id.* According to the Senate Report, the amendments were intended to "allow the Secretary to begin the study of the health status of these veterans by identifying a population of veterans who served in Vietnam, without first having to determine whether each was, without question, exposed to Agent Orange in Vietnam." 1981 S. REP. at 26.

B. The Health Study Protocol and Pilot Study. Following enactment of the 1981 Amendments, the Secretary entered into a contract with the Centers for Disease Control ("the Center") to design a protocol for the epidemiological investigation. The Center's Health Study Protocol, completed in November 1983, proposed three studies to evaluate the health of Vietnam veterans, one of which was the "Agent Orange" Study, designed to examine the effects of exposure to Agent Orange and other herbicides on veterans' health. *See* United States Department of Health and Human Services, Public Health Service, Centers for Disease Control, Protocol for Epidemiologic Studies of the Health of Vietnam Veterans (November 1983) at 1, 6-9 ("Health Study Protocol").[5]

[5] The two other studies—the "Vietnam Experience" study, to assess the "possible health effects of the general Vietnam experience," and the "Sarcoma/Lymphoma" or "Selected Cancers" study,

To isolate the effects of dioxin exposure, the Center needed to distinguish between groups of Vietnam veterans who were similar except for their level of dioxin exposure. *See supra* n.2. The Health Study Protocol proposed to use military records to divide a sample of Vietnam veterans into those who were likely exposed to herbicides in Vietnam and those likely not exposed and then to compare the health of the two cohorts. Health Study Protocol at 6-7, 10-15. The Center planned to review battalion journal files and morning reports to locate companies at various times during the Vietnam conflict and to determine the presence or absence of individuals within the company. Utilizing herbicide usage reports such as aircraft spraying records to estimate the location and timing of herbicide applications, the Center planned to fit veterans into the "likely exposed" or "likely not exposed" cohort "according to the measure of their company's distance in time and space from any herbicide applications." *Id.* at 6. To measure the possible health effects of dioxins, the Center would then compare the medical histories of "likely exposed" and "likely not exposed" veterans based on review of mortality records, health interviews, medical examinations, and laboratory tests. *Id.* at 20-25.

The Health Study Protocol cautioned that certain "obstacles" prevented the Center from adopting the "ideal" design for an Agent Orange cohort study, which would have compared one group free from all exposure to another group subjected to "meaningful" exposure to herbicides. These obstacles included the difficulty of defining "meaningful exposure" and the uncertainty about whether exposed veterans were comparable to unexposed veterans in other characteristics that might affect health. Most significant for purposes of these appeals, the Protocol

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to "evaluate the risk of contracting soft tissue sarcoma and lymphoma among Vietnam veterans (and/or those exposed to herbicides)"—have been completed and are not at issue in these appeals.

noted that the "uneven quality" of the military records, including gaps in company records and errors in herbicide usage records, meant that "the categorization of individuals with respect to their potential for herbicide exposure will be uncertain and will forever remain so." *Id.* at 6. The Health Study Protocol concluded that "[s]ince many of the proposed procedures are untested, modification, indeed even a recommendation not to proceed with an Agent Orange Study, may be required. . . ." *Id.* at 11.

The Center's initial review, conducted from 1983 to 1986, confirmed its concern that inadequacies in the military documentation would likely make identification of appropriate cohorts impossible. Informed of these difficulties, OTA advised Congress in September 1985 that if the difficulties in evaluating exposure were not resolved, OTA might conclude that the [sic] "it is impossible to study the effects of Agent Orange." OTA subsequently suggested that the Center postpone any "major new phase" of its Agent Orange Study until it had devised an appropriate means of estimating exposure and recommend that instead of proceeding with the interviews of study subjects scheduled to begin in January 1986, the Center conduct a pilot study to test the methods and results of its initial exposure assessments. Accordingly, the Environmental Support Group of the United States Army and Joint Services developed a pilot study, at the Center's request, to identify "heavily exposed personnel." Completed in mid-1986, the pilot study ranked veterans based on their number of "hits," or opportunities for exposure to Agent Orange; veterans with the largest number of "hits" were classified as those most likely to have faced heavy exposure.[6]

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[6] A veteran received a score of one "hit" for each day that his company was located within 2 kilometers of a reported Agent Orange spray line applied within the previous 6 days.

In early 1986, the Agent Orange Working Group ("Working Group"), formed by the President to carry out his responsibilities under the 1979 Act, convened a Science Subpanel on Exposure Assessment ("Science Subpanel") to evaluate the Center's exposure assessment methods and review the results of the pilot study. In a May 26, 1986, letter to the Working Group, the Science Subpanel concluded that two problems jeopardized the Center's Agent Orange Study: first, the potential for "considerable" misclassification because of unit dispersion and incomplete records of spray operations; and second, the fact that the Center's records review showed that most veterans had never been exposed to a "hit," as defined by the Center, and thus "the paucity of clearly exposed combat veterans make it questionable whether a sufficient number can be assembled to conduct an epidemiological study of the type originally designed." The Science Subpanel noted that recent scientific advances might enable the Center more accurately to identify cohorts of likely exposed and likely unexposed veterans, but that given the problems with current identification methods, "any study of ground troops, which is dependent upon military records for the assessment of exposure to herbicides, [should] not be conducted without an additional method to verify exposure."

C. The TCDD Validation Study. Responding to the recommendations from OTA and the Science Subpanel not to proceed with a military records-based study without some independent verification, the Center developed a protocol to compare current serum TCDD levels in veterans' blood. Assuming TCDD survived in the blood for several years, the Center postulated that veterans who faced "heavy" exposure could be expected to have higher serum TCDD levels than lesser exposed veterans even twenty years after their exposure to Agent Orange.[7] The

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[7] Although the Center did not know the precise half-life of TCDD at the time it developed its TCDD protocol, it determined in the course of the study that TCDD has an average half-life of

Center used both the pilot study's "hit"-based exposure indices and veterans' self-reported exposure estimates to divide a set of Vietnam veterans into "low hit," "medium hit," and "high hit" subsets and, for comparison, also examined a group of non-Vietnam veterans of the same era.

The results of the TCDD study confirmed the Center's suspicions that neither military records nor self-reporting could adequately differentiate between veterans who were and were not likely exposed to Agent Orange in Vietnam. U.S. Department of Health Human Services, Centers for Disease Control, Comparison of Serum Levels of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin With Indirect Estimates of Agent Orange Exposure Among Vietnam Veterans: Final Report (August 1987) ("TCDD Report"). The Center found "no meaningful association" between veterans' current TCDD levels and the exposure indices developed through either military records or self-reporting.[8] *Id.* at 1. Besides failing to validate the use of military records as exposure indicators, the TCDD study reinforced the conclusion that ground troops faced little likelihood of "heavy" exposure to Agent Orange. *Id.* at 2. The Center thus concluded that it could not conduct the cohort Agent Orange Study that it had originally planned:

> The findings of this study and the conclusion from the Agent Orange Working Group Science Subpanel

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seven years. The half-life of a substance is "the time required by the body, tissue, or organ to metabolize or inactivate half the amount of a substance taken in." F.A. DAVIS, TABER'S CYCLOPEDIC MEDICAL DICTIONARY at 717 (1985).

[8] The Center controlled for differences such as age, race, region of current residence, body mass index, alcohol use, smoking history, and self-reported civilian occupational and home exposure to herbicides. *Id.* at 23. The study also considered the impact of other factors that might lead to study bias—group selection, laboratory error or measurement bias, variability in half-life, selection or participation bias, and sample size—and concluded that none of these factors likely influenced the results. *Id.* at 27-30.

> report on exposure assessment (June 1986) do not identify any method for using military records or self-reported exposure to distinguish between U.S. Army ground combat troops who were and were not exposed to Agent Orange in Vietnam, as would be needed for a cohort study of possible health effects.

Id. at 1.

In a review of the TCDD study, OTA agreed that "a large-scale epidemiological study to look for effects of Agent Orange in ground troops who served in Vietnam" was currently impossible, and cautioned that any future studies "should be narrowly focused on specific, testable hypotheses, and cannot have the aim of generalizability to all or most ground troops." *Id.* at 9. On October 29, 1987, the director of the Center reported to the Secretary the Center's concurrence with OTA and the Working Group that the Agent Orange Study "cannot be conducted" and that the Center had begun "the close-out process" for its Agent Orange Study.

D. The Secretary's decision. In December 1987, the Department of Medicine and Surgery in the Veterans Administration recommended a halt to all further studies of the effects of Agent Orange (other than the Air Force's Ranch Hand study). Because the results of the TCDD report "make it exceedingly unlikely that any method will satisfactorily distinguish between exposed and unexposed Vietnam veterans," the Department of Medicine and Surgery concluded that "a scientifically meaningful epidemiological study of the possible health effects of Agent Orange cannot be conducted."

On February 9, 1988, the Secretary sent the TCDD report, along with correspondence from OTA and the Working Group, to the Chairman of the House Committee on Veterans' Affairs. In a cover letter the Secretary stated that:

> Despite our efforts, . . . no one has successfully identified a large enough group of Vietnam veterans known to have been exposed to Agent Orange or other herbicides to allow the preparation of a protocol and the conduct of an epidemiological study as required by Public Law 96-151.[9] I must, therefore, advise you that no scientifically sound study can be undertaken and request that the [Veterans Administration] be relieved of the requirement to do this research. This opinion coincides with that of the Office of Technology Assessment, as expressed in their comments of September 1987, and with the June 3, 1987, comments of the interagency Agent Orange Working Group.

A week later, the Secretary formally notified the Chairman of the decision to discontinue work on the Center's Agent Orange Study. On February 19, 1988, in his third annual report to Congress on the status of the Center's three-part Health Study, the Secretary repeated his conclusion that "based on the results of the . . . TCDD Validation Study, . . . an [Agent Orange Study] cannot be conducted so as to achieve a scientifically sound conclusion regarding the possible adverse health effects of exposure of Vietnam veterans to Agent Orange." [10]

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[9] The Secretary described Ranch Hand veterans as "the sole group of veterans . . . available for the successful epidemiological investigation envisaged by the Congress."

[10] In accord with the Secretary's recommendation that any allocated but unexpended funds be reallocated to either "the U.S. Air Force's Ranch Hand Study's blood dioxin levels research or other research on Agent Orange and closely related subjects," Congress in 1988 transferred $3,000,000 of the unexpended funds for blood tests in the Ranch Hand study and $1,000,000 for "a survey of scientific evidence, studies, and literature" regarding the health effects of possible herbicide exposure in Vietnam, to be conducted by an independent scientific entity under contract with the VA, "pursuant to a law enacted after the date of the enactment of this Act." *See* § 1201 of Pub. L. No. 100-687, 102 Stat. 4105, 4125 (1988). Subsequently, in 1991, Congress authorized the National

Appellants thereafter filed suit, contending that the Secretary unlawfully abandoned the Center's Agent Orange Study based on the wrong legal standard, that the Secretary lacked authority to terminate the Agent Orange Study before submitting a health results report to Congress, and that his decision was contrary to the Administrative Procedure Act, 5 U.S.C. § 706. Following the district court's grant of summary judgment for appellees, appellants filed these consolidated appeals.

II.

In addressing appellants' challenges to the grant of summary judgment in favor of appellees, our review is *de novo*. *Diamond v. Atwood*, 43 F.3d 1538, 1540 (D.C. Cir. 1995); *Shields v. Eli Lilly & Co.*, 895 F.2d 1463, 1466 (D.C. Cir. 1990). Thus, the limited questions before the court are whether the Secretary adopted a "permissible" interpretation of the 1979 and 1981 Acts, *see Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 841-42 (1984), and, if so, whether, as a matter of law, the Secretary's decision in February 1988 to abandon the Center's Agent Orange Study was arbitrary and capricious, an abuse of discretion, or otherwise contrary to law. 5 U.S.C. § 706(2)(A); *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971); *Dr. Pepper/Seven-Up Companies, Inc. v. FTC*, 991 F.2d 859, 862 (D.C. Cir. 1993). In reviewing the Secretary's decision to abandon the study, the court's task is to determine whether the Secretary "examine[d] the relevant data," and made a "rational connection between the facts found and the

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Academy of Sciences to review and evaluate the available scientific studies regarding the health effects of herbicide exposure and required the Secretary to enact regulations establishing a presumption that any malady correlated with herbicide exposure is service-related. Agent Orange Act of 1991, Pub. L. No. 102-4, 105 Stat. 11 (1991) (codified as amended at 38 U.S.C. § 1116 & note (Supp. IV 1992)).

choice made." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (internal quotations omitted); *see also Citizens to Preserve Overton Park v. Volpe*, 401 U.S. at 416. Given the nature of the scientific expertise brought to bear on the issue of whether to continue the Center's Agent Orange Study, the court's review is at its most deferential. *Baltimore Gas & Electric Co. v. Natural Resources Defense Council, Inc.*, 462 U.S. 87, 103 (1983).

A. Reporting "results". Appellants contend that the Secretary violated the statute by abandoning the Center's Agent Orange Study before reporting actual health results to Congress. Section 307(b)(2) of the 1979 Act provides:

> Not later than twenty-four months after the date of the approval of the protocol . . . and annually thereafter, the [Secretary] shall submit to the appropriate committees of the Congress a report containing (A) a description of the *results thus far obtained under the study* conducted pursuant to this subsection, and (B) such comments and recommendations as the [Secretary] considers appropriate in light of such results. [Emphasis added].

Appellants maintain that the word "results" in § 307 (b)(2) means substantive health results, and hence, that the Secretary lacked authority to abandon the Center's Agent Orange Study before reporting to Congress the Center's conclusions about adverse health effects of Agent Orange and other herbicides on Vietnam veterans. *See id.* § 307(a)(3) *as amended by* 1981 Amendments § 401 (a)(2) (Secretary may discontinue the study "after the submission of the first report under subsection (b)(2)"). The Secretary interprets "results" under § 307(b)(2) to include the progress made thus far to carry out the study and maintains that he fulfilled § 307(b)(2)'s requirement when he provided Congress with a progress report on February 13, 1986.

In reviewing the Secretary's interpretation of § 307 (b)(2), we apply the standard of review set forth in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 841-42 (1984). Because, contrary to appellants' contentions, neither the plain language nor the structure of the statute makes clear Congress' intent to confine "results" to "health results" in mandating reports by the Secretary, the court must defer to the Secretary's interpretation if it "is based on a permissible construction of the statute." *Id.* The Secretary's interpretation accordingly invokes our deference.[11] Because the Secretary's interpretation of "results" is consistent with Congress' use of that term in the statute, *see* 1979 Act § 307(b)(2), and appellants' construction of congressional intent would lead to absurd results, the Secretary's interpretation withstands scrutiny.

The Secretary's interpretation that "results thus far obtained under the study" means the results of the Secretary's efforts pursuant to the statute is not an impermissible construction of § 307(b)(2). The word "results" is hardly a technical term of art, but one of common parlance subject to multiple meanings. Thus, "results" may include conclusions that the Secretary has reached in the course of efforts to carry out the Center's Agent Orange Study and are not, as appellants suggest, necessarily limited to "health results" produced by that study. The "result" of the TCDD study, for example, is the conclusion that current blood serum levels bear no relation to military records-based exposure assessments. The "results" of the pilot study are the index of "hit"-based

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[11] Although *Chevron* deference would not apply if the Secretary had adopted this interpretation solely for purposes of litigation, *see City of Kansas City, Mo. v. HUD*, 923 F.2d 188, 192 (D.C. Cir. 1991), the interpretation at issue appeared in the Secretary's February 13, 1986, report to Congress, in which he stated: "As required by Section 307 of Public Law 96-151 . . . I am sending you and your committee the first status report and its appendices" on the Agent Orange Study.

exposure assessments and the conclusion that most ground troops did not have the opportunity for heavy exposure to Agent Orange. Both studies led, in one sense, to "results . . . obtained under the study" since they followed the Secretary's approval of the Health Study Protocol and represented efforts to develop data that would enable the production of scientifically valid epidemiological conclusions.

Put otherwise, an epidemiological study on long-term health effects produces many types of "results" that the Secretary could report to Congress. The fact that the statute requires the Secretary to submit annual reports on the "results thus far obtained under the study" comports with the view that Congress wanted regular progress reports on the results of the Secretary's efforts, whether or not such reports contained substantive health results. *See* 1979 Act § 307(b)(2). Indeed, the Secretary's submission of various reports to Congress between 1986 and 1988 alerted Congress that the development of scientifically valid health results depended on the identification of reliable indices of cohort exposure. The language of § 307(a)(3) also supports the Secretary's interpretation; by allowing the Secretary to abandon the study after submission of the first report if he finds it unlikely that the study will yield "significant new information on the long-term health effects of exposure to dioxins," subsection (a)(3) appears to contemplate that the Secretary's first report may not itself contain information on adverse health effects.[12] *Id.* § 307(a)(3).

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[12] The fact that Congress directed the Secretary to consider various administrative actions based on the "results" reported under § 307(b)(2) does not make his interpretation of "results" unreasonable. *See id.* § 307(b)(2)(B), (b)(3). The statute requires the Secretary to submit "comments and recommendations [that the Secretary] considers appropriate in light of such results," *id.* § 307(b)(2)(B), and to give notice and comment of "actions, *if any*," that the Secretary proposes to take in response to the results. *Id.* § 307(b)(3) (emphasis added). The Secretary fulfilled

Appellants' contrary statutory arguments are unpersuasive. First, appellants contend that because the statute requires OTA to submit "updates" on the status of unapproved protocols, *id.* § 307(a)(2)(B)(ii), Congress must have intended "results" under § 307(b)(2) to mean more than a progress report. Although courts generally presume that " 'Congress acted intentionally and purposely' " when particular language in one section of a statute is omitted in another section. *Russello v. United States*, 464 U.S. 16, 23 (1983) (quoting *United States v. Wong Kim Bo*, 472 F.2d 720, 722 (5th Cir. 1972)), the statutory differences between the reporting requirements imposed on OTA and the Secretary are consistent with the Secretary's interpretation of "results." OTA's "updates" on the status of protocol revisions reflect only the status of the Secretary's plans to conduct the study; because the Center's Agent Orange Study has not yet begun, the reports cannot contain its "results." The Secretary's reports, by contrast, reflect information gathered in the process of conducting the study, which can fairly be labeled "results thus far obtained under the study."

Similarly unpersuasive is appellants' second contention that the differences between the Agent Orange statute and a 1983 statute providing for an epidemiological study of the health effects of radiation exposure, Veterans Health Care Amendments of 1983, Pub. L. 98-160 § 601, 97 Stat. 1006-08 (1983) (codified as amended at 38 U.S.C. § 219 note (1988)) (the "1983 Act"), demon-

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the requirements of § 307(b)(2)(B) in his first and subsequent progress reports, when he informed Congress of the proposed TCDD study and its results, notified Congress of the Center's Agent Orange Study's abandonment, and recommended that the legislature reallocate unused funds. *See supra* n.10. Subsection (b)(3) makes clear that the Secretary need not recommend *any* "action" based on the study's "results." It is consistent with this subsection for the Secretary to recommend no rulemaking action, given the "result" that the effects of Agent Orange could not presently be ascertained.

strate that Congress intended to require the Secretary to provide "health results" in his reports pursuant to § 307(b)(2) of the 1979 Act. Although the 1983 Act explicitly gives the Secretary discretion not to conduct a study if he finds a scientifically valid study infeasible, *id.* § 601(a)(1)(B), the fact that the Secretary could not abandon the epidemiological study without developing a protocol and reporting some kind of results does not mean that the "results" reported must be "health results." Nor is the 1983 Act's requirement of reports on "the progress . . . and any results" of the radiation study, *id.* § 601(a)(5)(A), inconsistent with interpreting "results" as used in § 307(b)(2) of the 1979 Act to include data and conclusions other than "health results." Absent either a conflict between the 1983 Act and the Secretary's interpretation or a clear contrary meaning of the word "results," we will not read the 1983 Act to preclude the reasonable interpretation adopted by the Secretary. *Compare West Virginia University Hosp., Inc. v. Casey*, 499 U.S. 83, 99-101 (1991).[13]

Indeed, the reasonableness of the Secretary's interpretation is manifest in light of the implausibility of the alternative interpretation proposed by appellants. *See United States v. Wilson*, 112 S. Ct. 1351, 1354 (1992). Under their interpretation, Congress intended to require the Secretary to proceed with the Center's Agent Orange Study and present its "results" to Congress even when the Secretary knew that the inability to identify necessary data

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[13] Finally, while Congress' failure to consider the possibility that the study might not ultimately yield substantive health results cannot form the basis for an interpretation contrary to the plain meaning of a statute, *see West Virginia Univ. Hosp., Inc. v. Casey*, 499 U.S. at 100-01, where the Secretary's interpretation comports with the language of the statute and an alternative interpretation would produce absurd results, the fact that Congress did not specifically consider the issue is irrelevant. *See id.; see also Natural Resources Defense Council, Inc. v. EPA*, 725 F.2d 761, 770 (D.C. Cir. 1984).

would render the results scientifically useless. Not only do the 1981 Amendments and the Secretary's reports to Congress make clear that Congress knew that the underlying data was problematic, but the various reporting requirements in the statute highlight the unreasonableness of appellants' unsupported assumption that Congress intended the Secretary to devote resources to a study that the Secretary, the Center, the congressional OTA, and the President's Working Group had all concluded could not yield the valid scientific results mandated by statute. Other provisions in the statute also suggest that Congress did not intend the Secretary to conduct a study unless it was a scientifically valid one. Congress expressly required the Secretary to conduct the study pursuant to a protocol approved by the director of OTA. 1979 Act § 307(a)(2)(A)(i). The director of the OTA was to assess scientific validity in his approval or disapproval of the proposed protocol. *Id.* § 307(a)(2)(B)(i). Also, Congress directed the President to monitor the study for the purpose of assuring that the study was scientifically valid. *Id.* § 307(c). Assuming the accuracy of the Secretary's conclusion that a scientifically valid Agent Orange study was infeasible, in the absence of a clear statutory command, the Secretary was not required to proceed with a study that by all indications would not advance scientific knowledge solely to fulfill the obligation to report "results."

Because the language and purpose of the statute support the Secretary's interpretation of "results" as the progress made thus far in the Center's Agent Orange Study, we conclude that the Secretary satisfied his initial reporting obligation under § 307(b)(2) of the 1979 Act when he submitted a report to Congress on February 13, 1986, describing the results of efforts to carry out the epidemiological study.

B. The Standard. Appellants contend that the Secretary acted contrary to law because he decided to abandon

the study based on the repealed standard of the 1979 Act (focusing on individual veterans who "were exposed to . . . dioxins")[14] instead of the liberalized standard adopted in the 1981 Amendments (examining health effects that "may have resulted from exposure").[15] Appellants rely on the fact that in his February 9, 1988, letter to the Chairman of the House Committee on Veterans' Affairs, the Secretary reported that he had not "successfully identified a large enough group of Vietnam *known to have been exposed* to Agent Orange or other herbicides to allow the preparation of a protocol and the conduct of an epidemiological study as required by Public Law 96-151." They also point to the beginning of the Secretary's letter where he referred to the repealed legal standard in discussing the efforts made under the 1979 Act "[s]ince 1980." Appellants' emphasis on this language, however, overlooks other language in the Secretary's letter that demonstrates that he based his decision on concerns about scientific validity rather than compliance with the pre-1981 statutory mandate, that the numerous reports before the Secretary recommended abandoning the Center's Agent Orange Study because compliance with the 1981 mandate was not scientifically possible, and that the TCDD study confirmed that military records could not yield adequate exposure indices.

As appellants point out, a reviewing court "must judge the propriety of [agency] action solely by the grounds invoked by the agency." *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947). It is equally true, however, that "we will uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 285-86 (1974). Hence, even if some of the agency's remarks might appear erroneous when read in

[14] 1979 Act § 307(a)(1) (amended 1981).

[15] 1981 Amendments § 401(a)(1).

isolation, the court will uphold agency action that, "[c]onsidered in its entirety," is based on appropriate considerations and otherwise complies with relevant statutes and the Administrative Procedures Act. *District Lodge 64 v. NLRB*, 949 F.2d 441, 446 (D.C. Cir. 1991). Such consideration here indicates that the Secretary did not base his decision on the repealed statutory standard.

First, that the Secretary's decision focused on problems with the cohort study designed pursuant to the 1981 Amendments is evident from his letter's reference to the identification of a large enough *group* of veterans, as distinct from the focus of the original 1979 Act on individuals who had been exposed. The Secretary expressly incorporated by reference a separate statement by the Veterans' Administration's Department of Medicine and Surgery that refers to the 1981 standard and discusses the efforts to "estimate the likelihood" of exposure to Agent Orange. He noted, moreover, at the beginning of his letter that completion of the TCDD study "enabled the V[eterans'] A[dministration] to complete an attempt to determine directly and specifically whether exposure to Agent Orange had an adverse effect on the health of Vietnam veterans," thereby indicating that as addressed in the TCDD study, verification of exposure data remained the important factor under the 1981 standard. In context, therefore, the Secretary's reference to exposure suggests that the inability to distinguish exposure levels among different groups of veterans meant that he could not establish the data base necessary for a scientifically valid study.

Second, the Secretary attached to his February 9, 1988, letter to Congress OTA's September 1987 report and the Working Group's comments of June 3, 1987; both documents recommended abandonment of the Center's Agent Orange Study, not because of an inability to ensure that each study subject was exposed to Agent Orange, but because current identification methods provided no scientifically valid means of differentiating groups of veterans

based on the degree of exposure, and thus the long-term health effects of Agent Orange and other herbicides on the study subjects could not be assessed. OTA and the Working Group thus concluded that "no scientifically sound study can be undertaken."

Third, the Secretary also attached to his February 9, 1988, letter to Congress the TCDD validation study, which confirmed that compliance with the 1981 statutory mandate was not feasible because the Center was unable to classify groups of veterans based on their degree of exposure to Agent Orange and other herbicides. The Center compared individual hit scores as well as median TCDD levels by company, by the company in which the veteran spent the most time, and by the company in which the veteran had the most "hits." The Center concluded that neither individuals with higher "hit" scores nor companies with predicted higher levels of exposure had, on average, significantly higher TCDD levels in their blood, and therefore that it could not develop the data base needed for a cohort epidemiological study.

Viewing the Secretary's February 9, 1988, letter together with the documents that the incorporated by reference thus makes clear that notwithstanding the Secretary's reference to the inability to identify veterans "*known to have been exposed*" to Agent Orange and other herbicides, his decision to abandon the Center's Agent Orange Study rested on the inability to identify study cohorts based on the degree of exposure. Although Congress anticipated that the 1981 Amendments would remove the threshold problem of identifying individual veterans who were exposed to Agent Orange, 1981 S. REP. 26, 33, the amendments left in place the requirement that the study yield scientifically valid results. Appellants appear to ignore or underestimate the significance of the fact that even under the 1981 Amendments the epidemiological study depended on exposure data, and that the Center's Agent Orange Study relied on the ability to determine the degree of ex-

posure experienced by different groups of veterans. Thus, notwithstanding the Secretary's unfortunate choice of some words in his February 9 letter, the references noted by appellants cannot be divorced from the Secretary's references to "a large enough group" and the enclosed statement of the Department of Science and Medicine or fairly understood without regard to the supporting materials on which he relied in making his decision. For these reasons, we conclude that the Secretary did not rely on an improper legal standard in deciding to abandon the Agent Orange epidemiological study.

C. Abandoning the original Agent Orange Study. Because appellants' other challenges fail, the success of their appeals turns on whether, as a matter of law, the Secretary acted arbitrarily and capriciously in determining in February 1988 that a scientifically valid epidemiological study was infeasible. Appellants maintain that the "risk" of misclassification cannot alone make an epidemiological study scientifically invalid and that the Secretary had no evidence to support the conclusion that the degree of misclassification was sufficiently high to make valid scientific results unobtainable.

The statute vests the Secretary with broad discretion to abandon the entire epidemiological study if, after his initial report to Congress, the Secretary determines that the study will yield no useful scientific results.

> The study . . . shall be continued for as long after the submission of the first report under subsection (b)(2) as the [Secretary] may determine reasonable in light of the possibility of developing through such study significant new information on the long-term adverse health effects of exposure to dioxins.

1979 Act § 307(a)(3) *as amended by* 1981 Amendments § 401(a)(2). Given this broad discretion, the scope of our review of the Secretary's decision to abandon one component of the Health Study Protocol is particularly limited.

See Kreis v. Secretary of Air Force, 866 F.2d 1508, 1514 (D.C. Cir. 1989) ("[i]t is simply more difficult to say that the Secretary has acted arbitrarily if he is authorized to act '*when he considers it necessary . . .*' than it is if he is required to act whenever a court determines that certain objective conditions are met") (emphasis in original). Applying this standard, we conclude that the Secretary did not act arbitrarily and capriciously in abandoning the Center's Agent Orange Study after determining, in view of the available reports, studies and recommendations, that it was unlikely to produce scientifically valid conclusions about the long-term effects of exposure to Agent Orange and other herbicides on Vietnam veterans' health. 1979 Act § 307(a)(3), (c).

The information available to the Secretary indicated that from its inception, the Center's Agent Orange Study was confronted with identification difficulties that persisted through an additional pilot study and completion of the TCDD study. The Center's Health Study Protocol anticipated that its records-based method of exposure assessment might require "modification, indeed even a recommendation not to proceed with an Agent Orange study . . . ." Health Study Protocol at 11. The initial review of military records confirmed the Center's concern that it might not succeed in identifying cohorts of veterans who faced a greater likelihood of exposure to Agent Orange and other herbicides than comparable cohorts of their peers and thus would have no way of distinguishing the health effects of exposure to Agent Orange or other herbicides, as needed for an epidemiological study. The congressional OTA and the President's Working Group supported this assessment. The pilot study, which the Center commissioned to evaluate its exposure assessment methods, highlighted the inexactitude in the military records and revealed not only that unit dispersion and inadequate spray records made classification difficult, but also that most veterans (other than the Ranch Hands) never had the opportunity for sig-

nificant Agent Orange exposure. The TCDD validation study, in turn, confirmed that the military records-based assessments bore no relationship to current (and therefore past) levels of Agent Orange in veterans' blood. With the evidence suggesting that the military records did not provide accurate exposure indices, and with no evidence that an alternative method existed to identify a sufficient number of veterans who were likely exposed to Agent Orange or other herbicides, the Secretary could reasonably conclude, in concurrence with the Center, OTA, and the Working Group, that the originally planned epidemiological Agent Orange Study was infeasible.

The fact that the TCDD study left open the possibility that military records might accurately identify exposed veterans at low levels of exposure does not alter this conclusion. Because the purpose of the TCDD study was to *validate* the records-based exposure indices, the study, while not ruling out the possibility that military records provided accurate exposure indices at low levels of exposure, did not provide the verification of low-level exposure indices that the Center, OTA, and the Working Group had deemed necessary to justify a cohort study using military records.

Appellants nevertheless fault the Secretary for his failure to determine precisely how much misclassification inheres in the military records. According to appellants, the Science Subpanel implicitly drew a line "on the epidemiological risk continuum" beyond which the degree of misclassification made scientific validity unachievable.[16] They

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[16] Appellants also rely on a statement in the 1986 Science Subpanel report that it "felt that an additional method to verify exposure is required" as indicating that the Secretary acted on the basis of amorphous "feelings" rather than evidence in the record. The Secretary, however, based his conclusion that an exposure verification method was necessary on more than the Science Subpanel's "feelings." OTA had similarly concluded that, because of misclassification problems, an independent method of

maintain that *Ethyl Corp. v. EPA*, 541 F.2d 1, 38-40 (D.C. Cir. 1976), and other cases require the Secretary to make this line explicit and to support his determination with evidence in the record. *Ethyl*, which involved an agency rule setting a particular numerical value for acceptable blood lead levels, 541 F.2d at 38, offers little guidance here. Whereas *Ethyl* addressed whether the agency had a rational basis for the chosen numerical value, the question in these appeals is whether the Secretary had a rational basis for determining that no known method existed to verify whether the military records-based assessments differentiated between exposed and non-exposed veterans in the way necessary for a cohort study. The TCDD study was designed, in part, to accomplish what appellants charge the Secretary should have done: determine the degree of correlation (and therefore the degree of misclassification) between military records and TCDD exposure. As the TCDD study illustrates, the Secretary has no way of knowing the precise degree of misclassification. The Secretary knows only that inaccuracies and imprecision in the military records make it impossible to determine whether a particular group of veterans is more likely to have been exposed to Agent Orange and other herbicides than a comparable cohort of their peers. That he did not pursue still other alternatives, at best vaguely identified by appellants, does not demonstrate that the Secretary acted unreasonably in concluding in February 1988 that the Center's Agent Orange Study should be abandoned.[17]

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exposure assessment or some means of verifying the records-based exposure estimates was needed. In addition, the TCDD study, which post-dated the Science Subpanel report, confirmed that military records did not give reliable estimates of exposure to Agent Orange among ground troops and that most ground troops had never faced meaningful exposure to Agent Orange or other herbicides.

[17] Appellants proffer the affidavit of Dr. Zena A. Stein, who states that "[m]isclassification problems, like those at issue in the

For these reasons we conclude that appellants have failed to show that when the Secretary made his decision, after extensive efforts to identify and classify the data required for an epidemiological study that focused solely on the long-term health effects of dioxin exposure, the Secretary acted unreasonably or contrary to law in abandoning the Center's Agent Orange Study. To the extent that Vietnam veterans as a group faced higher exposure to Agent Orange and other herbicides than other groups of veterans, the Center's Vietnam Experience and Selected Cancers Studies were designed, in part, to detect health effects that may have resulted from such exposure. In addition, the Air Force's Ranch Hands study was examining the one group of veterans who faced heavy exposure to Agent Orange and other herbicides. Based on the data

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[Center's] exposure study . . . do not necessarily invalidate any justification of the study." Affidavit at 6-7. Dr. Stein, however, concedes that "a valid study must meet a minimum threshold of probability and comparability" between exposed and unexposed cohorts with respect to the fact of exposure, amount and duration of exposure, and other personal characteristics and influences that might affect individuals' health. *Id.* at 2-4. Significantly, Dr. Stein does not criticize the methodology used by the Center in reviewing the military records, and she acknowledges that misclassification might preclude a valid Agent Orange Study if "the misclassification problems were much greater than anticipated and outlined in" the Health Study Protocol. *Id.* at 7.

Nor does appellants' assertion that the National Academy of Sciences has now proposed to conduct an Agent Orange Study based on military records discredit the Secretary's decision, which was made several years before the Academy issued its preliminary proposal. Moreover, in the single page from the proposal that appears in the record, the Academy acknowledges that it "does not know whether the approach it proposes will prove valid or whether new methods will identify a sufficient number of highly exposed Vietnam veterans for an epidemiologic study." National Academy of Sciences, Institute of Medicine, Veterans and Agent Orange: Health Effects of Herbicides Used in Vietnam (1993). This is hardly a criticism of the Secretary's approach, let alone the identification of a fundamental flaw in the studies and conclusions on which the Secretary relied.

available to the Secretary in February 1988, however, the Secretary could reasonably conclude that it was impossible to identify groups of Vietnam veterans who were similar except for their levels of dioxin exposure, as required for the cohort tests necessary to ascertain the health effects of dioxins through a scientifically valid Agent Orange Study.

Accordingly, because appellants have failed to present a material issue of fact or to demonstrate that appellees were not entitled to judgment as a matter of law as to whether the Secretary's decision was arbitrary, capricious, an abuse of discretion, or otherwise contrary to law, we affirm the grant of summary judgment to appellees.

[Filed Jun. 7, 1995]

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 93-5404

THE AMERICAN LEGION,
Appellant

v.

EDWARD DERWINSKI, SECRETARY,
DEPARTMENT OF VETERANS AFFAIRS, *et al.*,
Appellees

and consolidated case No. 94-5013

Before: Edwards, *Chief Judge*, Randolph and Rogers, *Circuit Judges*.

ORDER

It is ORDERED, *sua sponte*, that the opinion filed herein on April 25, 1995 is amended, as follows:

In the caption of the consolidated case

delete

"Vietnam Veterans of America; Harold A. Butler; Carol Ridolfi-Delaney; Marel J. Macki; Beverly Nehmer,"

substitute

"William (Bill) Atwell; Harold A. Butler; Carol Delaney-Ridolfi; Julio Gonzales; Marel J. Macki;

Beverly Nehmer; Daniel Orta; Paul L. Sutton," to the listing of appellants.

Per Curiam

FOR THE COURT:
MARK J. LANGER
Clerk

By: /s/ Illegible
Deputy Clerk

APPENDIX B

[Filed Jul. 19, 1993]

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Actions
No. 90-1808 SSH
No. 90-1809 SSH
(consolidated)

THE AMERICAN LEGION,
Plaintiffs,

v.

EDWARD J. DERWINSKI, Secretary,
United States Department of Veterans Affairs, *et al.*,
Defendants.

VIETNAM VETERANS OF AMERICA, *et al.*,
Plaintiffs,

v.

EDWARD J. DERWINSKI, Secretary,
United States Department of Veterans Affairs, *et al.*,
Defendants.

OPINION

Before the Court are defendants' motion to dismiss or, in the alternative, for summary judgment; plaintiffs' motion to supplement the record; plaintiffs' second motion to supplement the record; plaintiffs' motion for discovery; defendants' motion for a protective order staying dis-

covery pending a ruling on defendants' dispositive motion; and the motion by certain members of Congress to reconsider the Magistrate Judge's order denying leave to file a memorandum as *amici curiae*.[1] Upon consideration of the motions, the Court grants defendants' motion for summary judgment, grants in part plaintiffs' motion to supplement the record, and denies the remaining motions.

Summary judgment may be granted only if the pleadings and evidence "show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). In considering a summary judgment motion, all evidence and the inferences to be drawn from it must be considered in a light most favorable to the nonmoving party. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). Summary judgment cannot be granted "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Although findings of fact and conclusions of law are unnecessary in ruling on a summary judgment motion, the Court sets forth its reasoning. *See* Fed. R. Civ. P. 52(a).

Background

Plaintiffs are The American Legion, Vietnam Veterans of America, and nine individually-named Vietnam veterans and widows of veterans.[2] Defendants are the Secretaries of the Department of Veterans Affairs (VA) and the Department of Health and Human Services (HHS),

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[1] On September 3, 1992, the Magistrate Judge issued a Report and Recommendation that resolved seven of the 11 pending nondispositive motions. The Magistrate Judge recommended that the Court resolve the remaining four nondispositive motions in conjunction with the dispositive motion. Both sides agree with this recommendation, as does the Court.

[2] The individual plaintiffs are Bill Atwell, Harold A. Butler, Carol Delaney-Ridolfi, Julio Gonzales, Marel J. Macki, Beverly Nehmer, Laura O'Callaghan, Daniel Orta, and Paul L. Sutton.

the Directors of the Centers for Disease Control (CDC) and its Center for Environmental Health and Injury Control, and the United States. Plaintiffs challenge defendants' action terminating a congressionally-mandated study to investigate any long-term health effects in Vietnam veterans that may have resulted from exposure to phenoxy herbicides, including Agent Orange. *See* Pub. L. No. 96-151, 93 Stat. 1097 (1979) (amended 1981, 1984), 38 U.S.C. § 219 note.[3] Plaintiffs seek a declatory judgment that defendants' decision to cancel the study violated the authorizing statute and the Administrative Procedure Act (APA), 5 U.S.C. § 706. Plaintiffs also seek an injunctive order directing defendants to conduct the study.[4]

For two years following enactment of the authorizing statute, the VA's contractor for the study encountered significant difficulties identifying veterans who had actually been exposed to herbicides. As a result, in 1981 Congress loosened the requirement of actual exposure to allow the study to commence. *See* Pub. L. 97-72, 95 Stat. 1061 (1981). In January 1983, the VA entered into a contract with the CDC to design and execute the study. The CDC developed a protocol intended to iden-

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[3] The statute requires in part that the Secretary of Veterans Affairs:

> design a protocol for and conduct an epidemiological study of any long-term adverse health effects in [Vietnam veterans] as such health effects may result from exposure to phenoxy herbicides (including the herbicide known as Agent Orange) and the class of chemicals known as the dioxins produced during the manufacture of such herbicides.

38 U.S.C. § 219 note (a) (1) (A).

[4] In addition, plaintiffs seek an order requiring the VA, after completing the study, to review and amend disability and death compensation regulations as the study results warrant, and to readjudicate veterans' claims that have been denied but which might raise issues in light of the study's results or the amended regulations.

tify discrete cohorts of veterans who were and were not likely to have been exposed to Agent Orange in Vietnam. The CDC planned to determine whether those likely to have been exposed suffered from any distinct health effects. By early 1984 the congressional Office of Technology Assessment (OTA) had approved the CDC's protocol as required by the authorizing statute. 38 U.S.C. § 219 note (a)(2)(A)(i).

The CDC had qualified the study's potential within the protocol, noting that "[s]ince many of the proposed procedures are untested, modifications, indeed even a recommendation not to proceed with the Agent Orange study, may be required after pilot assessments." Erickson Decl. Ex. A at 11. Working with the United States Army and Joint Services Environmental Support Group to match military records of troop locations and herbicide spraying, the CDC found that the records were more deficient than it had anticipated. The data indicated that troops were often dispersed 20 kilometers from the main company's location records. In addition, records contained gaps of company locations for various days. Eventually, the CDC sought to adjust the original protocol in 1985. In response to the CDC's proposed changes, the OTA demanded a revised protocol. Furthering the OTA position, in January 1986, the chairmen of the House Veterans' Affairs Committee and the Senate Committee on Veterans' Affairs requested the CDC to suspend activity on the principal study until after the OTA approved a new protocol.

In addition to the mandated OTA oversight, the authorizing statute charged the President with monitoring the Agent Orange exposure study to assure its scientific validity. 38 U.S.C. § 219 note (c). As a result, an interagency council of Cabinet and subcabinet level officers known as the White House Domestic Policy Council (DPC) had organized a subgroup, the Agent Orange Working Group (AOWG). In early 1986, following the

OTA's demand for a new protocol, the AOWG's Science panel convened a Subpanel on Exposure Assessment (Subpanel) to review the status of the study. The June 1986 Subpanel report and a companion pilot assessment disclosed a considerable potential for misclassification of exposed and non-exposed veterans. The study confirmed the difficulty of identifying reliable cohorts to examine. Subsequently, the AOWG Science panel concluded that an exposure study based on military records alone was not scientifically valid. The AOWG Science panel recommended that the CDC develop an independent verification method to determine the likelihood of veterans' exposure to Agent Orange.

Adopting the AOWG Science panel's recommendation in the summer of 1986, the CDC developed a validation study to verify the accuracy of exposure estimates based on military records. By measuring the 2,3,7,8-TCDD (dioxin) level in blood serum, the CDC could reasonably determine previous exposures to phenoxy herbicides. The study results showed no correlation between the military records' estimates of exposure to Agent Orange and the veterans' blood dioxin levels.

Based on the recommendation of the AOWG Science panel and the results of the blood dioxin verification study, the CDC concluded that a scientifically valid exposure study could not be performed. In August 1987, after reviewing these findings, the OTA Agent Orange Advisory Panel, the AOWG Science panel, and the AOWG all recommended that the Agent Orange exposure study be cancelled. On October 9, 1987, the AOWG initiated the process for terminating the contracts of the CDC study. The DPC approved the AOWG recommendation on November 5, 1987. The AOWG informed the congressional committees that the study had "proved scientifically impossible to do." Beach Decl. Exs. G and H at 1.

Subsequently, on November 24, 1987, the VA requested a written report from the CDC regarding the recommenda-

tion that no scientifically valid study could be performed.[5] In December 1987, the VA Department of Medicine and Surgery conducted an independent review of the CDC's findings and endorsed the recommendation. The VA Administrator notified the House Veterans' Affairs Committee and the Senate Committee on Veterans' Affairs in a February 9, 1988, letter that:

> no one has successfully identified a large enough group of Vietnam veterans known to have been exposed to Agent Orange or other herbicides to allow the preparation of a protocol and the conduct of an epidemiological study as required by Public Law 96-151. I must, therefore, advise you that no scientifically sound study can be undertaken and request that the VA be relieved of the requirement to do this research.

Hobson Decl. Ex. E at 1-2. On February 17, 1988, the VA notified the congressional committees that funds previously appropriated for the Agent Orange study would revert to the Treasury Department. Subsequently, Congress ordered those funds shifted to other veterans' studies "upon cancellation of that contract." Pub. L. No. 100-687, § 1201, 102 Stat. 4105, 4125 (1988).

Discussion

In response to plaintiffs' claims contesting the termination of the study, defendants contend that they are entitled

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[5] Defendants cite this information as evidence that the VA made the ultimate decision to cancel the study. *See* Defendants' Reply to Plaintiffs' Memorandum in Opposition to Defendants' Motion for Summary Judgment at 6. However, this material does not appear within the administrative record submitted by defendants or the supplemental exhibits which they provide. Rather, this information is presented in Plaintiffs' Exhibit 28. The Court, however, supplements the record with Plaintiffs' Exhibit 28. *See infra* part II.B.

to summary judgment on two grounds.[6] First, defendants claim that Congress ratified the decision to cancel the study. Second, they argue that their actions were rational and otherwise in accordance with law, and therefore did not violate the APA. The Court first addresses defendants' ratification claim and then examines the alleged APA violations.

I. *Congressional Ratification*

Defendants claim that they are entitled to summary judgment because Congress approved the decision to cancel the exposure study in 1988. Defendants contend that Congress ratified the cancellation when it transferred the funds originally appropriated for the Agent Orange exposure study to other veterans' studies. Plaintiffs assert that defendants have failed to satisfy the heavy burden required to demonstrate ratification by appropriation.

In *Associated Electric Cooperative, Inc. v. Morton*, this Circuit held that "ratification by appropriation will not be found unless prior knowledge of the specific disputed action can be clearly demonstrated and the appropriation plainly shows 'a purpose to bestow the precise authority which is claimed'." *Associated Elec. Coop. Inc. v. Morton*, 507 F.2d 1167, 1174 (D.C. Cir. 1974) (citations omitted), *cert. denied*, 423 U.S. 830 (1975). When Congress reappropriated the funds from the Agent Orange study, it made no reference to repealing the authorizing statute. Pub. L. No. 100-687, § 1201, 102 Stat. 4105, 4125 (1988). Viewing the evidence in the light most favorable

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[6] Defendants also move to dismiss, claiming that the CDC's design and methodology choices are committed to agency discretion and not subject to judicial review. *See* 5 U.S.C. § 701(a)(2). Plaintiffs deny that they challenge the legality of the CDC's actions. Although the Court finds that plaintiffs do challenge the CDC's actions, they do so only in an effort to establish that defendants acted arbitrarily and capriciously in concluding that no Agent Orange study could be scientifically valid. Therefore, the Court denies defendants' motion to dismiss.

to plaintiffs, the Court finds that there is a genuine issue of material fact in dispute as to whether Congress had the requisite purpose to repeal the substantive law which authorized the study. Thus, the Court concludes that summary judgment on the basis of defendants' congressional ratification argument is inappropriate.[7]

II. *Alleged Violations of the APA* [8]

Under the APA, reviewing courts generally must examine "final agency action." 5 U.S.C. § 704. Deferring judicial intervention until after the agency's final action permits the full exercise of the administrative process.

"[T]he task of the reviewing court is to apply the appropriate APA standard of review, 5 U.S.C. § 706, to the agency decision based on the record the agency presents to the reviewing court." *Florida Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985). The final agency action in this case may be characterized as an informal one, and the Court will set it aside only if it is " 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law' or if the action failed to meet statutory, procedural, or constitutional requirements." *Citizens To Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 414 (1971) (*citing* 5 U.S.C. § 706(2)(A), (B), (C), (D)). This standard is highly deferential. *See, e.g., Motor*

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[7] Upon consideration of the motion by certain members of Congress to reconsider the Magistrate Judge's order denying leave to file a memorandum as *amici curiae*, the Court upholds the order because it is not "clearly erroneous or contrary to law." *See* Fed. R. Civ. P. 72(a).

[8] Because neither the authorizing statute nor legislative history indicates any congressional intent to create a private cause of action under the Agent Orange exposure study statute, the Court does not recognize such a right. *See Middlesex County Sewerage Auth. v. Nat'l Sea Clammers Ass'n*, 453 U.S. 1, 13-15 (1981). As a result, plaintiffs' claims that defendants violated the authorizing statute are governed by the APA. 5 U.S.C. § 706(2)(A).

Vehicle Mfrs. Ass'n, Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983). Moreover, reviewing courts are to defer to reasonable agency interpretations of statutory schemes when the authorizing language is silent or ambiguous. *See Chevron, U.S.A., Inc. v. National Resources Defense Council*, 467 U.S. 837, 843 (1984).

As a threshold matter, the Court examines the parties' dispute regarding which governmental body made the final decision to cancel the Agent Orange exposure study. The Court then addresses the parties' conflict over the adequacy of the administrative record. Finally, the Court considers whether the decision to cancel the study was arbitrary, capricious, or otherwise not in accordance with law.

A. Final Agency Action

First, plaintiffs contend that determining which body made the decision to cancel the study, the DPC or the VA, is a genuine issue of material fact that precludes summary judgment. In their initial statement of material facts, defendants claimed that the DPC made the decision to cancel the study. In their amended statement of material facts, however, defendants withdrew this contention. Instead, they assert that the VA Administrator's decision to terminate the study was the final agency action reviewable by this Court.[9] Plaintiffs, however, claim that during

[9] The Court rejects plaintiffs' attempt to estop defendants from amending their statement of facts. Plaintiffs argue that if defendants recant earlier statements they thereby create a material issue of fact. *See Pyramid Sec. Ltd. v. IB Resolution, Inc.*, 924 F.2d 1114, 1123 (D.C. Cir. 1991) ("Courts have long held that a party may not create a material issue of fact simply by contradicting its prior sworn testimony." (citation omitted)), *cert. denied*, 112 S. Ct. 85 (1991). Defendants claim that their misstatements do not contradict sworn declarations but were "arguments contained in defendants' legal memoranda" that "resulted from honest error" on counsel's part. *See* Defendants' Opposition to Plaintiffs' Motion to Estop Defendants at 15. It is undisputed that the VA

a meeting on November 5, 1987, the DPC made the decision to cancel the Agent Orange exposure study. This DPC decision, plaintiffs assert, violates the statutory authority which restricts cancellation of the study to the VA Administrator. *See* 38 U.S.C. § 219 note (a)(3).[10] At the least, they claim that defendants' reversal regarding the finality of the DPC action is sufficient to create a genuine issue of material fact.

It is well settled that courts generally review final agency action which is the last, legal administrative action. *See, e.g., Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 882 (1990). Courts are averse to reviewing action prior to agency completion. Viewing the facts in the light most favorable to the plaintiffs, the Court assumes that the DPC made a decision to cancel the CDC study and to notify Congress thereof. However, this action by the DPC is not inconsistent with the VA's retention and execution of the final, legal authority to cancel the Agent

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Administrator had the sole statutory authority to cancel the study and that his letter of February 9, 1988, was the final action taken in announcing the cancellation. As such, defendants "offer persuasive reasons for believing the supposed correction." *Pyramid*, 924 F.2d at 1123. Therefore, the Court permits defendants' proposed amendments.

Even if the Court were to estop defendants from amending their statement of facts, the Court would still find that there is no genuine issue of material fact in dispute. The Court finds that, regardless of what the Beach declaration states that the DPC decided to tell Congress or how the Hobson declaration characterizes the VA's action, the VA nevertheless ultimately exercised its sole legal authority to cancel the study.

Plaintiffs also raise other facts purportedly in dispute, but the Court finds that they are likewise not material.

[10] The cancellation provision reads in part: "The study . . . shall be continued for as long . . . as the Administrator may determine reasonable in light of the possibility of developing through such study significant new information on the long-term adverse health effects of exposure to dioxins." 38 U.S.C. § 219 note (a)(3).

Orange exposure study. Following the DPC decision, on November 24, 1987, the VA requested a written report from the CDC with all data recommending cancellation of the study.[11] In December 1987, the VA Department of Medicine and Surgery conducted an independent study of the CDC's findings and concluded that no Agent Orange exposure study could be performed in a scientifically valid manner. The VA Administrator informed Congress in a February 9, 1988, letter of the decision that no scientifically valid study could be performed.

Had the VA not acted following the DPC decision to cancel, plaintiffs might have had a valid claim that the DPC made the final decision to cancel the study. However, the record demonstrates that the VA exercised the ultimate, binding decision to cancel the Agent Orange exposure study in February 1988. As plaintiffs and defendants recognize, the VA had the sole legal authority to terminate the Agent Orange exposure study. At the time that he chose to cancel the study, the VA Administrator could have used his power to continue the study regardless of the DPC finding. Moreover, even assuming that the DPC cancelled the CDC study, the VA could have initiated a new round of protocols to pursue the Agent Orange exposure study. Thus, the VA decision terminating the study was the final agency action, and it is reviewable by this Court. *See* 5 U.S.C. § 704.

B. *Adequacy of the Administrative Record*

Secondly, plaintiffs claim that even if the VA made the final agency action, the administrative record is insufficient for effective judicial review and they seek to amend it. Plaintiffs seek to augment the record with supplemental documents and declarations which they claim demonstrate that defendants acted arbitrarily and

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[11] *See supra* note 5.

capriciously in concluding that no scientifically valid study could be conducted. Plaintiffs also assert that some of the proposed supplemental exhibits reveal defendants' failure to consider relevant factors. Others, they contend, demonstrate that defendants relied on irrelevant considerations. Still others, according to the plaintiffs, provide important background information for the Court. Additionally, plaintiffs seek discovery primarily to inquire into any possibly improper DPC or White House pressures on the VA decision to cancel. Defendants contend, however, that the administrative record before the Court is adequate for effective judicial review.[12]

It is well established that courts are generally to review agency action based solely on the administrative record provided by the agency. *See, e.g., Camp v. Pitts*, 411 U.S. 138, 142 (1973) ("The focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court."); *Environmental Defense Fund, Inc. v. Costle*, 657 F.2d 275, 286 (D.C. Cir. 1981) ("There is no occasion for a judicial probe beyond the confines of a record which affords enough explanation to indicate whether the agency considered all relevant factors."). In addition, that record must be the one that was before the decision-maker. *See, e.g., Walter O. Boswell Memorial Hosp. v. Heckler*, 749 F.2d 788, 792 (D.C. Cir. 1984) ("If a court is to review an agency's action fairly, it should have before it neither more nor less information than did the agency when it made its decision.").

Courts have identified certain limited occasions that may allow the addition of supplemental information to the record. Among other reasons, the record may be supplemented:

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[12] Asserting that some documents were inadvertently omitted from the original record, defendants supplemented the record with five (Plaintiffs' Exhibits 14, 16, 23, 25, and 27) of the 29 documents plaintiffs seek to admit as well as two other documents.

> (1) when agency action is not adequately explained in the record before the court; (2) when the agency failed to consider factors which are relevant to its final decision; (3) when an agency considered evidence which it failed to include in the record; (4) when a case is so complex that a court needs more evidence to enable it to understand the issues clearly. . . .

Esch v. Yeutter, 876 F.2d 976, 991 (D.C. Cir. 1989) (footnote omitted). Moreover, the Ninth Circuit has found that the record may be supplemented when additional information "fully explicate[s] [the agency's] course of conduct" in reaching its decision. *Asarco, Inc. v. EPA*, 616 F.2d 1153, 1160 (9th Cir. 1980).

The Court finds that the approximately 2,000-page administrative record contains the VA Administrator's articulated explanation for his decision to cancel the exposure study. The record also includes the respective recommendations of the VA Department of Medicine and Surgery, the CDC, the OTA, and the AOWG Science Subpanel which were before the VA Administrator when he chose to terminate the study. The record includes, but is not limited to, evidence that defendants considered the relevant factors in selecting which veterans to study and in choosing the geographical area and time period to examine. It also contains defendants' reasoning for the necessity and relevance of the blood dioxin verification study. Plaintiffs' supplemental documents and declarations primarily challenge the scientific merits of the decision to cancel. Plaintiffs' other exhibits fail to contribute information pertinent to defendants' action or provide only peripheral background information. Accordingly, plaintiffs' motion to add documents to the record is largely denied.

The Court does, however, grant in part plaintiffs' motion to supplement the record. Plaintiffs' Exhibit 28 provides relevant information regarding the chain of events

in the VA's decision to terminate the study. The decision to terminate the Agent Orange exposure study involved numerous agencies and much interagency communication. Included in Plaintiffs' Exhibit 28 is the VA's request for a written report containing the CDC's data, which aids in fully explicating the VA's "course of conduct." *See Asarco, Inc.*, 616 F.2d at 1160. No other exhibit offered by plaintiffs yields information not already in the record regarding central steps in the VA's decisional process. Thus, for the limited purpose of more fully explicating the VA's decision, the Court supplements the administrative record only with Plaintiffs' Exhibit 28.[13] The Court therefore grants in part and denies in part plaintiffs' motion to supplement the record and denies plaintiffs' second motion to supplement the record.

Courts may grant discovery in agency review cases when, for example, there is a "strong showing of bad faith or improper behavior." *Citizens To Preserve Overton Park*, 401 U.S. at 420. Plaintiffs, however, submit no evidence that the VA Administrator relied on irrelevant factors in cancelling the study. They proffer only speculation that the DPC or the White House exerted pressure on the VA Administrator. Accordingly, the Court denies plaintiffs' motion for discovery.

C. *Defendants' Actions Were Not Arbitrary and Capricious Nor in Violation of the Law*

Plaintiffs claim that defendants violated the APA by acting arbitrarily and capriciously and not in accordance with law. *See* 5 U.S.C. § 706(2)(A). The Court disagrees. As noted, Rule 52(a) of the Federal Rules of Civil Procedure specifically makes findings and conclusions unnecessary in ruling on a motion for summary

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[13] Even without Exhibit 28 in the administrative record, the Court would still hold that the VA made the final decision to cancel the Agent Orange study.

judgment, but the Court elects to address plaintiffs' more meritorious arguments.

1. *Not Arbitrary and Capricious*

Among the actions which plaintiffs challenge is defendants' determination that a scientifically valid study would require independent verification to corroborate the exposure estimates based on military records. Additionally, plaintiffs challenge defendants' finding, based on the blood dioxin study, that no scientifically valid study could be performed. Finally, plaintiffs challenge the decision to cancel the study. Defendants argue that the scientific conclusions and the VA's decision to cancel the study were rational and reasoned.

The scope of review is "narrow" under the arbitrary and capricious standard. *Motor Vehicle Mfrs. Ass'n, Inc.*, 463 U.S. at 43. The reviewing court presumes agency action to be valid. *Citizens To Preserve Overton Park*, 401 U.S. at 415 ("Certainly, the [agency's] decision is entitled to a presumption of regularity."). Moreover, a court may not substitute its judgment for that of the agency. *Id.* at 416. Indeed, the Court need not decide if the decision to cancel the study is supported by a preponderance of the evidence or even whether it is supported by substantial evidence. Rather, the Court must sustain the decision if it has a rational basis in the evidence. *See Ethyl Corp. v. EPA*, 541 F.2d 1, 37 (D.C. Cir.) (en banc), *cert. denied*, 426 U.S. 941 (1976).

In addition, under the APA a reviewing court must not only consider the final agency action but also "preliminary" and "intermediate" agency actions. 5 U.S.C. § 704. As a result, the Court examines challenges to the scientific conclusions on which the VA relied. In examining such challenges to decisions involving an agency's area of special expertise at the frontiers of science, "a reviewing court must generally be at its most deferential." *Baltimore Gas & Elec. Co. v. National Resources Defense*

Council, 462 U.S. 87, 103 (1983); *see also Ethyl Corp.*, 541 F.2d at 36 ("We must look at the [agency's] decision not as the chemist, biologist or statistician that we are qualified neither by training nor experience to be, but as a reviewing court exercising our narrowly defined duty of holding agencies to certain minimal standards of rationality.").

One of the scientific conclusions that the plaintiffs challenge is the CDC's 1986 rejection of the scientific validity of exposure estimates based on military records. Plaintiffs contend that this conclusion is an arbitrary reversal from the CDC's original protocol. However, in concluding against sole reliance on the military records, the CDC considered the results of the June 1986 Subpanel report. The Subpanel report delineated three years of new data compiled by abstracting military records in an effort to match troop locations with herbicide spraying. This additional evidence on the unreliability of the military records established a rational basis for the CDC's 1986 decision that exposure estimates based on such records would not create scientifically valid exposure cohorts.

Plaintiffs also challenge the CDC's blood dioxin verification method and its finding that the study results indicated no scientifically valid exposure study could be performed. At the heart of plaintiffs' arguments, however, is a challenge to the scientific merit of the CDC's research rather than the rationality of its conclusion. Assuming, but not deciding, that plaintiffs may challenge the scientific merit, *see supra* note 6, the Court finds that the CDC's methodology and research exhibit reasoned decisionmaking and provide a rational basis for defendants' conclusion that a meaningful scientific study could not be performed.

In addition, plaintiffs also challenge the VA's decision to cancel the study. As noted, the authorizing statute provides that "[t]he study . . . shall be continued for as long . . . as the Administrator may determine reasonable

in light of the possibility of developing through such study significant new information on the long-term health effects of exposure to dioxins." 38 U.S.C. § 219 note (a)(3). Having considered the evidence and recommendations of the AOWG, the CDC, the OTA Agent Orange Advisory Panel, and the VA's Department of Medicine and Surgery, the Administrator concluded that no scientifically valid study could be performed. The Court finds that this decision to cancel was reasoned and rational. Thus the Court finds that neither the scientific conclusions leading up to the VA's decision to terminate the study nor the Administrator's final decision were "arbitrary and capricious." [14]

2. *Not Otherwise in Violation of Law*

Plaintiffs also assert that defendants' interpretation of the statutory scheme violates the authorizing statute and consequently the APA's requirement that agency action be in accordance with law. *See* 5 U.S.C. § 706(2)(A). They contend that defendants' failure to submit an initial report to Congress explaining the "results thus far obtained under the study" is one such violation. 38 U.S.C. § 219 note (a)(3), (b)(2). Defendants claim that in mandating such a report, Congress did not intend to require commencement of the study if no such study could be conducted with scientific validity. Instead, defendants argue that Congress required the report as a progress account, which defendants submitted.

"[I]f the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Chevron*, 467 U.S. at 843. The Court finds that defendants' construction of the statute was a "reasonable interpretation" of the provision. *Id.* at 844. The statute requires the President to assure the study's scientific validity. 38 U.S.C. § 219 note (c). In

[14] The Court rejects as meritless plaintiffs' other claims that defendants acted in an arbitrary and capricious manner.

light of this requirement, defendants' interpretation of the mandated report as a program update is reasonable. Thus, the Court finds that defendants committed no statutory violation that would breach the APA.[15] Accordingly the Court grants defendants' motion for summary judgment.[16]

Conclusion

For the reasons stated, the Court grants in part plaintiffs' motion to supplement the record as to Plaintiffs' Exhibit 28 and denies the remainder of the motion. The Court also denies plaintiffs' second motion to supplement the record, plaintiffs' motion for discovery, and the motion by certain members of Congress to reconsider the Magistrate Judge's order denying leave to file a memorandum as *amici curiae*. However, finding no genuine issue of material fact in dispute and finding in favor of defendants as a matter of law, the Court grants defendants' motion for summary judgment. An appropriate Order accompanies this Opinion.

/s/ Stanley S. Harris
STANLEY S. HARRIS
United States District Judge

Date: Jul. 19, 1993

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[15] The Court rejects plaintiffs' other statutory violation claims.

[16] As the Court grants defendants' motion for summary judgment, it denies as moot defendants' motion for a protective order staying discovery pending a ruling on the dispositive motion.

APPENDIX C

[Filed Jul. 19, 1993]

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Actions
No. 90-1808 SSH
No. 90-1809 SSH
(consolidated)

THE AMERICAN LEGION, *et al.*,
Plaintiffs,

v.

EDWARD J. DERWINSKI, Secretary, United States Department of Veterans Affairs, *et al.*,
Defendants.

VIETNAM VETERANS OF AMERICA, *et al.*,
Plaintiffs,

v.

EDWARD J. DERWINSKI, Secretary, United States Department of Veterans Affairs, *et al.*,
Defendants.

ORDER

For the reasons stated in the Court's accompanying Opinion, it hereby is

ORDERED, that plaintiffs' motion to supplement the record is granted in part and denied in part, and the ad-

ministrative record is supplemented with Plaintiffs' Exhibit 28. It hereby further is

ORDERED, that plaintiffs' second motion to supplement the record is denied. It hereby further is

ORDERED, that plaintiffs' motion for discovery is denied. It hereby further is

ORDERED, that the motion by certain members of Congress to reconsider the Magistrate Judge's order denying leave to file a memorandum as *amici curiae* is denied. It hereby further is

ORDERED, that defendants' motion for a protective order staying discovery pending a ruling on defendants' dispositive motion is denied as moot. It hereby further is

ORDERED, that defendants' motion for summary judgment is granted and the case is dismissed.

SO ORDERED.

/s/ Stanley S. Harris
STANLEY S. HARRIS
United States District Judge

Date: Jul. 19, 1993

APPENDIX D

[Filed Apr. 25, 1995]

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 93-5404

THE AMERICAN LEGION,
Appellant

v.

EDWARD DERWINSKI, Secretary,
Department of Veterans Affairs, *et al.*,
Appellees

And Consolidated Case 94-5013

ORDER

It is ORDERED on the Court's own motion, that the Clerk shall withhold issuance of the mandate herein until seven days after disposition of any timely petition for rehearing. See D.C. Cir. R. 41(a) (January 1, 1994). This instruction to the Clerk is without prejudice to the right of any party at any time to move for expedited issuance of the mandate for good cause shown.

FOR THE COURT:
MARK J. LANGER
Clerk

By: /s/ Eva Brown
Deputy Clerk

APPENDIX E

SUPREME COURT OF THE UNITED STATES
OFFICE OF THE CLERK
Washington, DC 20543

WILLIAM K. SUTER
Clerk of the Court

Area Code 202 479-3011

June 19, 1995

Mr. Gershon M. Ratner
National Veterans Legal
2001 S Street, Suite 610
Washington, DC 20009

Re: American Legion
v. Jesse Brown, Secretary of
Veterans Affairs, et al.
Application No. A-959

Dear Mr. Ratner:

The application for an extension of time within which to file a petition for a writ of certiorari in the above-entitled case has been presented to the Chief Justice, who on June 19, 1995, extended the time to and including August 23, 1995.

* * * *

Sincerely,

WILLIAM K. SUTER
Clerk

By /s/ Troy D. Cahill
TROY D. CAHILL
Assistant Clerk

APPENDIX F

STATUTORY PROVISIONS

Veterans' Health Programs Extension and Improvement Act of 1979, Pub. L. 96-151, § 307 (as amended):

38 U.S.C.A. § 527 Note

"(a)(1)(A) The Administrator of Veterans' Affairs shall design a protocol for and conduct an epidemiological study of any long-term adverse health effects in humans of service in the Armed Forces of the United States in the Republic of Vietnam during the period of the Vietnam conflict as such health effects may result from exposure to phenoxy herbicides (including the herbicide known as Agent Orange) and the class of chemicals known as the dioxins produced during the manufacture of such herbicides. In conducting such study, the Administrator may expand the scope of the study to include an evaluation of any long-term adverse health effects in humans of such service as such health effects may result from other factors involved in such service, including exposure to other herbicides, chemicals, medications, or environmental hazards or conditions. The Administrator may also include in the study an evaluation of the means of detecting and treating adverse health effects found through the study.

"(B) The Administrator shall also conduct a comprehensive review and scientific analysis of the literature covering other studies relating to whether there may be long-term adverse health effects in humans from exposure to phenoxy herbicides (including the herbicide known as Agent Orange) and the class of chemicals known as the dioxins produced during the manufacture of such herbicides. In conducting such review and analysis, the Administrator may expand the scope of such review and analysis to include a review and analysis of the literature covering other studies relating to whether there may be

long-term adverse health effects in humans from other factors involved in service in the Armed Forces of the United States in the Republic of Vietnam during the period of the Vietnam conflict or in other comparable situations involving one or more of the factors described in the second sentence of subparagraph (A). The Administrator may also include a review and analysis of the means of detecting and treating adverse health effects found through any study covered by either such review and analysis.

"(2)(A)(i) The study conducted pursuant to paragraph (1) shall be conducted in accordance with a protocol approved by the Director of the Office of Technology Assessment.

"(ii) The Director shall monitor the conduct of such study in order to assure compliance with such protocol.

"(B)(i) Concurrent with the approval or disapproval of any protocol under subparagraph (A)(i), the Director of the Office of Technology Assessment shall submit to the appropriate committees of the Congress a report explaining the basis for the Director's action in approving or disapproving such protocol and providing the Director's conclusions regarding the scientific validity and objectivity of such protocol.

"(ii) In the event that the Director has not approved such protocol during the one hundred and eighty days following the date of the enactment of this Act [Dec. 20, 1979], the Director shall (I) submit to the appropriate committees of the Congress a report describing the reasons why the Director has not given such approval, and (II) submit an update report on such initial report each sixty days thereafter until such protocol is approved.

"(C) The Director shall submit to the appropriate committees of the Congress, at each of the times specified in the second sentence of this subparagraph, a report on the Director's monitoring of the conduct of such study

pursuant to subparagraph (A)(ii). A report under the preceding sentence shall be submitted before the end of the six-month period beginning on the date of the approval of such protocol by the Director, before the end of the twelve-month period beginning on such date, and annually thereafter until such study is completed or terminated.

"(3) The study conducted pursuant to paragraph (1) shall be continued for as long after the submission of the first report under subsection (b)(2) as the Administrator may determine reasonable in light of the possibility of developing through such study significant new information on the long-term adverse health effects of exposure to dioxins.

"(b)(1) Not later than twelve months after the date of the enactment of this Act [Dec. 20, 1979], the Administrator shall submit to the appropriate committees of the Congress a report on the literature review and analysis conducted under subsection (a)(1).

"(2) Not later than twenty-four months after the date of the approval of the protocol pursuant to subsection (a)(2)(A)(i) and annually thereafter, the Administrator shall submit to the appropriate committees of the Congress a report containing (A) a description of the results thus far obtained under the study conducted pursuant to such subsection, and (B) such comments and recommendations for administrative or legislative action, or both, as the Administrator considers appropriate in light of such results.

"(3) Immediately after the submission of each report under paragraph (2), the Administrator, based on the results described in such report and the comments and recommendations included therein and any other available pertinent information, shall evaluate the need for any amendments to regulations, prescribed pursuant to section 5 of the Veterans' Dioxin and Radiation Exposure

Compensation Standards Act, [section 5 of Pub.L. 98-542, set out as a note under section 1154 of this title] for the resolution of claims for service connection based on the exposure specified in subsection (a)(1)(A) of such section. To the extent that the Administrator determines that any amendments to such regulations are needed, the Administrator, not later than 90 days after such submission, shall develop and publish in the Federal Register, for public review and comment, proposed amendments to such regulations.

"(4) The first report submitted under paragraph (2) shall include the Administrator's recommendation, and reasons therefor, with respect to whether the authority to provide care and services under and by virtue of section 610(a)(5) of title 38, United States Code [now section 1710(a)(5) of this title], should be extended beyond the expiration period specified by section 610(e)(3) of such title [now section 1710(e)(3) of this title].

"(c) For the purpose of assuring that any study carried out by the Federal Government with respect to the adverse health effects in humans of exposure to dioxins is scientifically valid and is conducted with efficiency and objectivity, the President shall assure that—

"(1) the study conducted pursuant to subsection (a) is fully coordinated with studies which are planned, are being conducted, or have been completed by other departments, agencies, and instrumentalities of the Federal Government and which pertain to the adverse health effects in humans of exposure to dioxins; and

"(2) all appropriate coordination and consultation is accomplished between and among the Administrator and the heads of such departments, agencies, and instrumentalities that may be engaged, during the conduct of the study carried out pursuant to subsection (a), in a design, conduct, monitoring, or evaluation of such dioxin-exposure studies.

"(d) There are authorized to be appropriated such sums as may be necessary for the conduct of the study required by subsection (a)."

Pub. L. 96-151, § 307, Dec. 20, 1979, 93 Stat. 1097:

AGENT ORANGE STUDY

SEC. 307. (a)(1) The Administrator of Veterans' Affairs shall design a protocol for and conduct an epidemiological study of persons who, while serving in the Armed Forces of the United States during the period of the Vietnam conflict, were exposed to any of the class of chemicals known as "the dioxins" produced during the manufacture of the various phenoxy herbicides (including the herbicide known as "Agent Orange") to determine if there may be long-term adverse health effects in such persons from such exposure. The Administrator shall also conduct a comprehensive review and scientific analysis of the literature covering other studies relating to whether there may be long-term adverse health effects in humans from exposure to such dioxins or other dioxins.

(2)(A)(i) The study conducted pursuant to paragraph (1) shall be conducted in accordance with a protocol approved by the Director of the Office of Technology Assessment.

(ii) The Director shall monitor the conduct of such study in order to assure compliance with such protocol.

(B)(i) Concurrent with the approval or disapproval of any protocol under subparagraph (A)(i), the Director of the Office of Technology Assessment shall submit to the appropriate committees of the Congress a report explaining the basis for the Director's action in approving or disapproving such protocol and providing the Director's conclusions regarding the scientific validity and objectivity of such protocol.

(ii) In the event that the Director has not approved such protocol during the one hundred and eighty days following the date of the enactment of this Act, the Director shall (I) submit to the appropriate committees of the Congress a report describing the reasons why the Director has not given such approval, and (II) submit

an update report on such initial report each sixty days thereafter until such protocol is approved.

(C) The Director shall submit to the appropriate committees of the Congress, at each of the times specified in the second sentence of this subparagraph, a report on the Director's monitoring of the conduct of such study pursuant to subparagraph (A)(ii). A report under the preceding sentence shall be submitted before the end of the six-month period beginning on the date of the approval of such protocol by the Director, before the end of the twelve-month period beginning on such date, and annually thereafter until such study is completed or terminated.

(3) The study conducted pursuant to paragraph (1) shall be continued for as long after the submission of the report under subsection (b)(2) as the Administrator may determine reasonable in light of the possibility of developing through such study significant new information on the long-term adverse health effects of exposure to dioxins.

(b)(1) Not later than twelve months after the date of the enactment of this Act, the Administrator shall submit to the appropriate committees of the Congress a report on the literature review and analysis conducted under subsection (a)(1).

(2) Not later than twenty-four months after the date of the approval of the protocol pursuant to subsection (a)(2)(A)(i) and annually thereafter, the Administrator shall submit to the appropriate committees of the Congress a report containing (A) a description of the results thus far obtained under the study conducted pursuant to such subsection, and (B) such comments and recommendations as the Administrator considers appropriate in light of such results.

(c) For the purpose of assuring that any study carried out by the Federal Government with respect to the adverse health effects in humans of exposure to dioxins is scientifically valid and is conducted with efficiency and objectivity, the President shall assure that—

(1) the study conducted pursuant to subsection (a) is fully coordinated with studies which are planned, are being conducted, or have been completed by other departments, agencies, and instrumentalities of the Federal Government and which pertain to the adverse health effects in humans of exposure to dioxins; and

(2) all appropriate coordination and consultation is accomplished between and among the Administrator and the heads of such departments, agencies, and instrumentalities that may be engaged, during the conduct of the study carried out pursuant to subsection (a), in the design, conduct, monitoring, or evaluation of such dioxin-exposure studies.

(d) There are authorized to be appropriated such sums as may be necessary for the conduct of the study required by subsection (a).

Approved December 20, 1979.

Pub. L. 97-72, § 401, Nov. 3, 1981, 95 Stat. 1061:

TITLE IV—MISCELLANEOUS PROVISIONS

EXPANSION OF SCOPE OF AGENT ORANGE STUDY

SEC. 401. (a)(1) Paragraph (1) of section 307(a) of the Veterans Health Programs Extension and Improvement Act of 1979 (Public Law 96-151; 93 Stat. 1097) is amended to read as follows:

"(1)(A) The Administrator of Veterans' Affairs shall design a protocol for and conduct an epidemiological study of any long-term adverse health effects in humans of service in the Armed Forces of the United States in the Republic of Vietnam during the period of the Vietnam conflict as such health effects may result from exposure to phenoxy herbicides (including the herbicide known as Agent Orange) and the class of chemicals known as the dioxins produced during the manufacture of such herbicides. In conducting such study, the Administrator may expand the scope of the study to include an evaluation of any long-term adverse health effects in humans of such service as such health effects may result from other factors involved in such service, including exposure to other herbicides, chemicals, medications, or environmental hazards or conditions. The Administrator may also include in the study an evaluation of the means of detecting and treating adverse health effects found through the study.

"(B) The Administrator shall also conduct a comprehensive review and scientific analysis of the literature covering other studies relating to whether there may be long-term adverse health effects in humans from exposure to phenoxy herbicides (including the herbicide known as Agent Orange) and the class of chemicals known as the dioxins produced during the manufacture of such herbicides. In conducting such review and analysis, the Ad-

ministrator may expand the scope of such review and analysis to include a review and analysis of the literature covering other studies relating to whether there may be long-term adverse health effects in humans from other factors involved in service in the Armed Forces of the United States in the Republic of Vietnam during the period of the Vietnam conflict or in other comparable situations involving one or more of the factors described in the second sentence of subparagraph (A). The Administrator may also include a review and analysis of the means of detecting and treating adverse health effects found through any study covered by either such review and analysis.".

(2) Paragraph (3) of such section is amended by inserting "first" after "submission of the".

(b) Section 307(b) of such Act is amended—

(1) by inserting "for administrative or legislative action, or both," in paragraph (2) after "recommendations"; and

(2) by adding at the end the following new paragraphs:

"(3) Not later than ninety days after the submission of each report under paragraph (2), the Administrator shall, based on the results described in such report and the comments and recommendations thereon and any other available pertinent information, publish in the Federal Register, for public review and comments, a description of actions, if any, that the Administrator proposes to take with respect to programs administered by the Veterans' Administration. Each such description shall include a justification or rationale for any such action the Administrator proposes to take.

("(4) The first report submitted under paragraph (2) shall include the Administrator's recommendation, and reasons therefor, with respect to whether the authority

to provide care and services under and by virtue of section 610(a)(5) of title 38, United States Code, should be extended beyond the expiration period specified by section 610(e)(3) of such title.".

Pub. L. 97-72, § 102, Nov. 3, 1981, 95 Stat. 1047:

VETERANS' HEALTH CARE, TRAINING, AND SMALL BUSINESS LOAN ACT OF 1981

MEDICAL CARE FOR DISABILITIES THAT MAY BE RELATED TO EXPOSURE TO AGENT ORANGE, CERTAIN OTHER HAZARDOUS SUBSTANCES, OR NUCLEAR RADIATION

SEC. 102. (a) Section 610 is amended—

(1) in subsection (a)—

(A) by striking out "and" at the end of the clause (4);

(B) by redesignating clause (5) as clause (6); and

(C) by inserting after clause (4) the following new clause (5):

"(5) a veteran who meets the conditions of subsection (e) of this section; and"; and

(2) by adding at the end the following new subsection:

"(e)(1)(A) Subject to paragraphs (2) and (3) of this subsection, a veteran—

"(i) who served on active duty in the Republic of Vietnam during the Vietnam era, and

"(ii) who the Administrator finds may have been exposed during such service to dioxin or was exposed during such service to a toxic substance found in a herbicide or defoliant used in connection with military purposes during such era,

may be furnished hospital care or nursing home care under subsection (a)(5) of this section for any disability, notwithstanding that there is insufficient medical evidence

to conclude that such disability may be associated with such exposure.

"(B) Subject to paragraphs (2) and (3) of this subsection, a veteran who the Administrator finds was exposed while serving on active duty to ionizing radiation from the detonation of a nuclear device in connection with such veteran's participation in the test of such a device or with the American occupation of Hiroshima and Nagasaki, Japan, during the period beginning on September 11, 1945, and ending on July 1, 1946, may be furnished hospital care or nursing home care under subsection (a)(5) of this section for any disability, notwithstanding that there is insufficient medical evidence to conclude that such disability may be associated with such exposure.

"(2) Hospital and nursing home care may not be provided under subsection (a)(5) of this section with respect to a disability that is found, in accordance with guidelines issued by the Chief Medical Director, to have resulted from a cause other than an exposure described in subparagraph (A) or (B) of paragraph (1) of this subsection.

"(3) Hospital and nursing home care and medical services may not be provided under or by virtue of subsection (a)(5) of this section after the end of the one-year period beginning on the date the Administrator submits to the appropriate committees of Congress the first report required by section 307(b)(2) of the Veterans Health Programs Extension and Improvement Act of 1979 (Public Law 96-151; 93 Stat. 1098).".

(b) Clause (4) of section 612(i) is amended to read as follows:

> "(4) To any veteran (A) who is a former prisoner of war, or (B) who is eligible for care under section 610(a)(5) of this title.".

Pub. L. 98-160, § 601, Nov. 21, 1983, 97 Stat. 1006:

TITLE VI—RADIATION EXPOSURE STUDY AND GUIDE

RADIATION EXPOSURE STUDY AND GUIDE

SEC. 601. (a)(1)(A) Subject to subparagraphs (B) and (C), the Administrator of Veterans' Affairs, through contracts or agreements with private or public agencies or persons and in consultation with the Director of the Office of Technology Assessment, shall provide for the conduct of epidemiological study of the long-term adverse health effects of exposure to ionizing radiation from the detonation of nuclear devices in connection with the test of such devices or in connection with the American occupation of Hiroshima and Nagasaki, Japan, during the period beginning on September 11, 1945, and ending on July 1, 1946, in persons who, while serving in the Armed Forces of the United States, were exposed to such radiation. Such study shall include, but not necessarily be limited to, a study of identifiable prevalent illnesses, including malignancies, in the persons exposed.

(B) If the Administrator, in consultation with the Director of the Office of Technology Assessment, determines that it is not feasible to conduct scientifically valid study of any or all of the matters required under subparagraph (A) to be studied—

> (i) the Administrator shall promptly submit to the appropriate committees of the Congress notice of that determination and the reasons therefor; and
>
> (ii) the Director, not later than 60 days after such notice is provided, shall submit to such committees a report evaluating and commenting on such determination.

(C) If the Administrator notifies the Congress of a determination or determinations made pursuant to sub-

paragraph (B), the matter or matters required under subparagraph (A) to be studied to which such determination or determinations apply shall not be required to be studied. If the Administrator notifies the Congress of a determination made pursuant to subparagraph (B) that, taken as a whole, study under subparagraph (A) is not scientifically feasible, the requirement in subparagraph (A) that the Administrator provide for the conduct of epidemiological study shall cease to have effect as if repealed by law.

(2) Not later than one year after the date of the enactment of this Act, the Administrator shall submit to the appropriate committees of the Congress a report on the development of a protocol or protocols for study under paragraph (1)(A). With respect to any such protocol under consideration for development, or in the process of development, that has not been completed by the end of such year, the report shall include an estimate of the completion date for such protocol and an estimate of the cost to be incurred in developing such protocol.

(3)(A) The Director of the Office of Technology Assessment shall monitor the development of the protocol or protocols for, and the conduct of, study under paragraph (1)(A) and shall submit to the appropriate committees of the Congress, at each of the times specified in the next sentence, a report on such monitoring. Reports under the preceding sentence shall be submitted within 6 months after the date of the enactment of this Act, within 12 months after such date, within 25 months after such date, and annually thereafter until such study is completed.

(B) If any protocol to which paragraph (2) applies (or any part of such protocol) is not completed by the end of the 12-month period beginning on the date of the enactment of this Act, the Director shall periodically submit to such committees reports on the status of the development of such proocol.

(4) When the Administrator has entered into a contract or agreement with an agency or person for the conduct of a study under paragraph (1)(A), the Administrator and such agency or person shall submit to the appropriate committees of the Congress a joint report containing a copy of the contract and an estimate f the total cost of such study.

(5)(A) Not later than 24 months after the date of the enactment of this Act, and annually thereafter, the Administrator shall submit to the appropriate committees of the Congress a report on the status of study under paragraph (1)(A). Such report shall contain (i) a description of the progress on and any results obtained under such study, and (ii) such comments, and such recommendations for administrative and legislative action, as the Administrator considers appropriate in light of such progress and results.

(B) The requirement in subparagraph (A) for the submission of annual reports shall expire upon the submission of a report after the completion of study under paragraph (1)(A).

(6) A contract to carry out study under paragraph (1)(A) may not be entered into unless (A) appropriations for payments under the contract have been provided in advance, or (B) the contract provides that the obligation of the United States to make payments under the contract is contingent upon the availability of funds appropriated for the making of such payments.

(7) There are authorized to be appropriated such sums as may be necessary for the conduct of study under subsection (a)(1)(A).

(b) Not later than one year after the date of the enactment of this Act, the Administrator shall develop and distribute to appropriate Veterans' Administration personnel an indexed reference guide, derived from existing pertinent research-result compilations, designed to

provide Veterans' Administration personnel who either furnish health care or adjudicate claims for benefits under title 38, United States Code, with readily usable information regarding the state of medical and other scientific information on any long-term adverse health effects in humans of exposure to ionizing radiation, including nuclear-device exposure, medical exposure, and occupational exposure.

(c)(1) For the purpose of ensuring that any study, research, or other activity carried out by the Federal Government with respect to adverse health effects in humans from exposure to ionizing radiation is scientifically valid and is conducted with efficiency and objectivity, the President shall ensure that—

(A) activities of the Veterans' Administration in connection with (i) study under subsection (a)(1)(A), (ii) the development of the guide required by subsection (b), and (iii) such additional research as may be identified, as a result of such study or the development of such guide or otherwise, as necessary for the resolution of questions regarding such effects are fully coordinated with studies and other activities which are planned, are being conducted, or have been completed by other departments, agencies, and instrumentalities of the Federal Government and which pertain to such effects, including the radioepidemiological tables mandated by section 7 of the Orphan Drug Act (Public Law 97-414; 96 Stat. 2059); and

(B) appropriate coordination and consultation occurs between and among the Administrator and the heads of such departments, agencies, and instrumentalities that may be engaged, during the conduct of study under subsection (a)(1)(A), in the design, conduct, monitoring, or evaluation of such radiation-exposure studies or related activities.

(2) Not later than 90 days after the date of the enactment of this Act, the President shall submit to the appropriate committees of the Congress a report containing a description of the steps taken and plans made to ensure the coordination and consultation required by paragraph (1).

Pub. L. 98-542, § 8, Oct. 24, 1984, 98 Stat. 2731:

AMENDMENTS TO REGULATIONS

SEC. 8. (a) Paragraph (3) of section 307(b) of the Veterans' Health Programs Extension and Improvement Act of 1979 (38 U.S.C. 219 note) is amended to read as follows:

"(3) Immediately after the submission of each report under paragraph (2), the Administrator, based on the results described in such report and the comments and recommendations included therein and any other available pertinent information, shall evaluate the need for any amendments to regulations, prescribed pursuant to section 5 of the Veterans' Dioxin and Radiation Exposure Compensation Standards Act, for the resolution of claims for service connection based on the exposure specified in subsection (a)(1)(A) of such action. To the extent that the Administrator determines that any amendments to such regulations are needed, the Administrator, not later than 90 days after such submission, shall develop and publish in the Federal Register, for public review and comment, proposed amendments to such regulations.".

(b) Paragraph (5) of section 601(a) of the Veterans' Health Care Amendments of 1983 (Public Law 98-160; 97 Stat. 1007) is amended by redesignating subparagraph (B) as subparagraph (C) and inserting after subparagraph (A) the following new subparagraph (B):

"(B) Immediately after the submission of each report under subparagraph (A), the Administrator, based on the results described in such report and the comments and recommendations included therein and any other available pertinent information, shall evaluate the need for any amendments to regulations, prescribed pursuant to section 5 of the Veterans' Dioxin and Radiation Exposure Compensation Standards Act, for the resolution of claims for service connection based on the exposure

specified in subsection (a)(1)(B) of such section. To the extent that the Administrator determines that any amendments to such regulations are needed, the Administrator, not later than 90 days after such submission, shall develop and publish in the Federal Register, for public review and comment, proposed amendments to such regulations.".

INTERIM BENEFITS FOR DISABILITY OR DEATH IN CERTAIN CASES

SEC. 9. (a)(1) In the case of a veteran—

(A) who served in the active military, naval, or air service in the Republic of Vietnam during the Vietnam era; and

(B) who has a disease described in subsection (b) that became manifest within one year after the date of the veteran's most recent departure from the Republic of Vietnam during that service,

the Administrator shall (except as provided in subsection (c)) pay a monthly disability benefit to the veteran in accordance with this section.

(2) If a veteran described in paragraph (1) dies from the disease, the Administrator shall pay a monthly death benefit to the survivors of the veteran in accordance with this section.

(b) The diseases referred to in subsection (a) are chloracne and porphyria cutanea tarda.

(c) Benefits may not be paid under this section with respect to a disease occurring in a veteran—

(1) where there is affirmative evidence that the disease was not incurred by the veteran during service in the Republic of Vietnam during the Vietnam era;

(2) where there is affirmative evidence to establish that an intercurrent injury or disease which is a

recognized cause of the disease was suffered by the veteran between the date of the veteran's most recent departure from the Republic of Vietnam during active military, naval, or air service and the onset of the disease; or

(3) if the Administrator determines, based on evidence in the veteran's service records and other records of the Department of Defense, that the veteran was not exposed to dioxin during active military, naval, or air service in the Republic of Vietnam during the Vietnam era.

(d)(1) A disability benefit payable to a veteran under this section for a disease described in subsection (b) shall be paid at the rate at which compensation would be payable under chapter 11 of title 38, United States Code, to that veteran for the disability resulting from that disease if the disability were determined to be service-connected.

(2) A death benefit payable under this section to the survivors of a veteran shall be paid to such survivors based upon the eligibility requirements (other than the requirement that death be the result of a service-connected or compensable disability) and at the rates that are applicable to dependency and indemnity compensation under chapter 13 of that title.

(e) A benefit may not be paid under this section with respect to a disease or the death of a veteran for any month for which compensation is payable to that veteran for that disease under chapter 11 of title 38, United States Code, or for which dependency and indemnity compensation is payable for that death under chapter 13 of such title.

(f) A disease establishing eligibility for a disability or death benefit under this section shall be treated for purposes of all other laws of the United States (other than chapters 11 and 13 of title 38, United States Code) as

if such disease were service connected. The receipt of a disability benefit under this section shall be treated for purposes of all other laws of the United States as if such benefit were compensation under chapter 11 of such title, and the receipt of a death benefit under this section shall be treated for purposes of all other laws of the United States as if such benefit were dependency and indemnity compensation under chapter 13 of title 38, United States Code.

(g) For the purposes of this section:

(1) The term "Administrator" means the Administrator of Veterans' Affairs.

(2) The term "Vietnam era" means the period beginning on August 5, 1964, and ending on May 7, 1975.

(3) The term "veteran" has the meaning given that term in paragraph (2) of section 101 of title 38, United States Code, and includes a person who died in the active military, naval, or air service.

(4) The terms "service-connected" and "active military, naval, or air service" have the meanings given those terms in paragraphs (16) and (24), respectively, of section 101 of title 38, United States Code.

Pub. L. 98-542, §§ 2, 5, Oct. 24, 1984, 98 Stat. 2727:

VETERANS' DIOXIN AND RADIATION EXPOSURE COMPENSATION STANDARDS ACT

FINDINGS

SEC. 2. The Congress makes the following findings:

(1) Veterans who served in the Republic of Vietnam during the Vietnam era and veterans who participated in atmospheric nuclear tests or the American occupation of Hiroshima or Nagasaki, Japan, are deeply concerned about possible long-term health effects of exposure to herbicides containing dioxin or to ionizing radiation.

(2) There is scientific and medical uncertainty regarding such long-term adverse health effects.

(3) In section 102 of Public Law 97-22, the Congress responded to that uncertainty by authorizing priority medical care at Veterans' Administration facilities for any disability of a veteran who may have been so exposed (even though there is insufficient medical evidence linking such disability with such exposure) unless the disability is found to have resulted from a cause other than the exposure.

(4) The Congress has further responded to that medical and scientific uncertainty by requiring, in section 307 of Public Law 96-151 and section 601 of Public Law 98-160, the conduct of thorough epidemiological studies of the health effects experienced by veterans in connection with exposure both to herbicides containing dioxin and (if not determined to be scientifically infeasible) to radiation, and by requiring in Public Law 97-414, the developing of radioepidemiological tables setting forth the probabilities of causation between various cancers and exposure to radiation.

REQUIREMENT FOR AND CONTENT OF REGULATIONS

SEC. 5.(a) In carrying out the responsibilities of the Administrator of Veterans' Affairs under section 354 (a)(2) of title 38, United States Code, and in order to promote consistency in claims processing and decisions, the Administrator shall prescribe regulations to—

(1) establish guidelines and (where appropriate) standards and criteria for the resolution of claims for benefits under laws administered by the Veterans' Administration where the criteria for eligibility for a benefit include a requirement that a death or disability be service connected and the claim of service connection is based on a veteran's exposure during service—

(A) in the Republic of Vietnam during the Vietnam era to a herbicide containing dioxin, or

(B) in connection with such veteran's participation in atmospheric nuclear tests or with the American occupation of Hiroshima or Nagasaki, Japan, prior to July 1, 1946, to ionizing radiation from the detonation of a nuclear device; and

(2) ensure that, with respect to those claims, the policy of the United States described in section 2(13) is carried out.

(b)(1)(A) The guidelines required to be established in regulations prescribed under this section shall include guidelines governing the evaluation of the findings of scientific studies relating to the possible increased risk of adverse health effects of exposure to herbicides containing dioxin or of exposure to ionizing radiation. Those guidelines shall require that, in the evaluation of those studies, the Administrator shall take into account whether the results are statistically significant, are capable of replication, and withstand peer review.

(B) The evaluations described in subparagraph (A) shall be made by the Administrator of Veterans' Affairs after receiving the advice of the appropriate panel of the Scientific Council of the Veterans' Advisory Committee on Environmental Hazards (established under section 6). Those evaluations shall be published in the notice section of the Federal Register.

(C) The standards and criteria required to be established in regulations prescribed under this section shall include provisions governing the use in the adjudication of individual claims of the Administrator's evaluations made under subparagraph (B).

(2)(A)(i) In prescribing regulations under this section, the Administrator (after receiving the advice of the Advisory Committee and of the appropriate panel of the Scientific Council of the Veterans' Advisory Committee on Environmental Hazards regarding the diseases described in subparagraph (B)) shall make determinations, based on sound medical and scientific evidence, with respect to each disease described in subparagraph (B) as to whether service connection shall, subject to division (ii) of this subparagraph, be granted in the adjudication of individual cases. In making determinations regarding such diseases, the Administrator shall give due regard to the need to maintain the policy of the United States with respect to the resolution of contested issues as set forth in section 2(13). The Administrator shall set forth in such regulations such determinations, with any specification (relating to exposure or other relevant matter) of limitations on the circumstances under which service connection shall be granted, and shall implement such determinations in accordance with such regulations.

(ii) If the Administrator makes a determination, pursuant to this subparagraph, that service connection shall be granted in the case of a disease described in subparagraph (B), the Administrator shall specify in such regu-

lations that, in the adjudication of individual cases, service connection shall not be granted where there is sufficient affirmative evidence to the contrary or evidence to establish that an intercurrent injury or disease which is a recognized cause of the described disease has been suffered between the date of separation from service and the onset of such disease or that the disability is due to the veteran's own willful misconduct.

(iii) With regard to each disease described in subparagraph (B), the Administrator shall include in the regulations prescribed under this section provisions specifying the factors to be considered in adjudicating issues relating to whether or not service connection should be granted in individual cases and the circumstances governing the granting of service connection for such disease.

(B) The diseases referred to in subparagraph (A) are those specified in section 2(5) and any other disease with respect to which the Administrator finds (after receiving and considering the advice of the appropriate panel of the Scientific Council established under section 6(d)(2)) that there is sound scientific or medical evidence indicating—

(i) a connection to exposure to a herbicide containing dioxin, in the case of a veteran who was exposed to that herbicide during such veteran's service in the Republic of Vietnam during the Vietnam era, or

(ii) a connection to exposure to ionizing radiation, in the case of a veteran who was exposed to ionizing radiation in connection with such veteran's participation in an atmospheric nuclear test or with the American occupation of Hiroshima or Nagasaki, Japan, before July 1, 1946.

(3) The regulations prescribed under this section shall include—

(A) specification of the maximum period of time after exposure to such herbicide or ionizing radiation for the development of those diseases; and

(B) a requirement that a claimant filing a claim based upon a veteran's exposure to a herbicide containing dioxin or to ionizing radiation from the detonation of a nuclear device may not be required to produce evidence substantiating the veteran's exposure during active military, naval, or air service if the information in the veteran's service records and other records of the Department of Defense is not inconsistent with the claim that the veteran was present where and when the claimed exposure occurred.

(c)(1) The Administrator of Veterans' Affairs shall develop the regulations required by this section (and any amendment to those regulations) through a public review and comment process in accordance with the provisions of section 553 of title 5, United States Code. That process may include consideration by the Administrator of the recommendations of the Veterans' Advisory Committee on Environmnetal Hazards and the Scientific Council thereof (established under section 6) with respect to the proposed regulations, and that process shall include consideration by the Administrator of the recommendations of the Committee and the Council with respect to the final regulations and proposed and final amendments to such regulations. The period for public review and comment shall be completed not later than ninety days after the proposed regulations or proposed amendments are published in the Federal Register.

(2)(A) Not later than one hundred and eighty days after the date of the enactment of this Act, the Administrator shall develop and publish in the Federal Register a proposed version of the regulations required to be prescribed by this section.

(B) Not later than three hundred days after the date of the enactment of this Act, the Administrator shall publish in the Federal Register the final regulations together with explanations of the bases for the guidelines, standards, and criteria contained therein required to be prescribed by this section.

Supreme Court, U.S.
FILED
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No. 95-254

In the Supreme Court of the United States

OCTOBER TERM, 1995

THE AMERICAN LEGION, ET AL., PETITIONERS

v.

JESSE BROWN, SECRETARY,
DEPARTMENT OF VETERANS AFFAIRS, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether the court of appeals correctly sustained the Secretary of Veterans Affairs' conclusion that he had the statutory authority to terminate a study of the human health effects of wartime exposure to herbicides such as Agent Orange.

2. Whether the Secretary's decision to terminate the study, on the ground that it was infeasible to design and conduct it in a way that would yield scientifically valid results, was arbitrary, capricious, or an abuse of discretion.

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BRIEF FOR THE RESPONDENTS IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-29a) is reported at 54 F.3d 789. The opinion and order of the district court (Pet. App. 30a-49a) are reported at 827 F. Supp. 805.

JURISDICTION

The judgment of the court of appeals was entered on April 25, 1995. On June 19, 1995, the Chief Justice extended the time for filing a petition for a writ of certiorari to and including August 25, 1995. The

petition was filed on August 11, 1995. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. In late 1979, Congress directed the Secretary of Veterans Affairs to

> design a protocol for and conduct an epidemiological study of persons who, while serving in the Armed Forces of the United States during the period of the Vietnam conflict, were exposed to any of the class of chemicals known as "the dioxins" produced during the manufacture of the various phenoxy herbicides (including the herbicide known as "Agent Orange") to determine if there may be long-term adverse health effects in such persons from such exposure.

Veterans Health Programs Extension and Improvement Act of 1979 (1979 Act), Pub. L. No. 96-151, § 307(a)(1), 93 Stat. 1097.[1] The study protocol was to be approved by the director of the congressional Office of Technology Assessment (OTA) (§ 307(a)(2)(A), 93 Stat. 1097), who was also required to report to the appropriate congressional committees on the scientific validity and objectivity of the protocol (§ 307(a)(2)(B)(i), 93 Stat. 1097). Congress also directed the President to assure that the study was coordinated with other government efforts to study the human health effects of dioxin exposure, to "assur[e] that any [such] study * * * is

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[1] As did the court of appeals (see Pet. App. 2a n.1), we use the present titles Secretary and Department of Veterans Affairs to refer to the former Veterans Administration and its Administrator.

scientifically valid and is conducted with efficiency and objectivity." § 307(c), 93 Stat. 1098.

The 1979 Act required the Secretary to provide Congress, within 24 months of approval of the protocol and annually thereafter, with "a description of the results thus far obtained under the study * * * [and] such comments and recommendations for administrative or legislative action, or both, as the [Secretary] considers appropriate in light of such results." 1979 Act § 307(b)(2), 93 Stat. 1098, as amended by the Veterans' Health Care, Training, and Small Business Loan Act of 1981 (1981 Act), Pub. L. No. 97-72, § 401(b)(1), 95 Stat. 1061. The Act further provided that the required study was to be "continued for as long after the submission of the first report under subsection (b)(2) as the [Secretary] may determine [to be] reasonable in light of the possibility of developing through such study significant new information on the long-term adverse health effects of exposure to dioxins." § 307(a)(3), 93 Stat. 1097, as amended by 1981 Act § 401(a)(2), 95 Stat. 1061.

In 1981, Congress recognized that difficulties in identifying individuals actually known to have been exposed to dioxins in Vietnam might make it difficult to conduct the study called for by the 1979 Act. See S. Rep. No. 89, 97th Cong., 1st Sess. 25 (1981). Congress therefore modified the mandate of the 1979 Act, in part to give the Secretary "discretionary authority" to "focus on service in Vietnam as the exposure circumstance being studied * * * while not, in any way, detracting from the study's focus, as already mandated, on agent orange." *Id.* at 26 (internal quotation marks omitted). The amended Act called for a study of "any long-term adverse health effects in humans of service * * * [in] Vietnam * * * as such

health effects may result from exposure to phenoxy herbicides (including the herbicide known as Agent Orange) and the class of chemicals known as the dioxins." 1979 Act § 307(a)(1)(A), as amended by 1981 Act § 401(a)(1), 95 Stat. 1061.[2]

2. The VA contracted with the federal Centers for Disease Control (CDC) to design and execute the study required by the 1979 and 1981 Acts. See C.A. App. 155. After various consultations, the CDC published an initial study protocol in November, 1983. See *id.* at 94, 99. That protocol proposed three separate studies: a Vietnam Experience Study, a Selected Cancers Study, and an Agent Orange Study. *Id.* at 102-105. Two of those component studies reflected the flexible mandate of the 1981 Act: The first compared the health of Vietnam veterans with that of other veterans, while the second examined correlations between military service in Vietnam and six types of cancer. *Id.* at 89-91. Both were successfully completed. *Ibid.*; see Pet. App. 5a n.5.

The third component study, at issue here, was designed as a direct investigation of the effects of exposure to Agent Orange. CDC's initial protocol noted that an ideal study would compare the health of a group of veterans known to have been exposed to meaningful amounts of Agent Orange with the health of an otherwise similar group who were free from such exposure. C.A. App. 100, 102. The protocol noted various problems in achieving that ideal, including the inherent limitations and uneven quality of available military records, but it proposed procedures for identifying cohorts of Vietnam veterans who

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[2] The 1979 Act, as amended, is reproduced at Pet. App. 52a-56a.

likely had and had not been meaningfully exposed to Agent Orange. *Id.* at 102-103.

The CDC recognized that those procedures were novel, and would need to be tested and validated before the main study could be undertaken. C.A. App. 107, 114E-114G. Indeed, the protocol explicitly noted that "modification, indeed even a recommendation not to proceed with an Agent Orange study, may be required after pilot study assessments." *Id.* at 107. In approving the CDC's initial protocol, the OTA expressed similar concerns about the adequacy of the proposed procedures for exposure assessment. See *id.* at 97; see also *id.* at 200-201.

The CDC did, in fact, encounter significant problems in using military records to evaluate Agent Orange exposure and to identify study cohorts of likely exposed and unexposed veterans.[3] See C.A. App. 207-208. In late 1985, the OTA expressed grave concerns about the issue, and advised several members of Congress that "[i]f there [were] no improvements, OTA [might] decide that the problems of deciding on exposure are so overwhelming that it is impossible to study the possible effects of Agent Orange." *Id.* at 207; see *id.* at 200-201. In February, 1986, the Secretary submitted to Congress the first of the progress reports required by the 1979 Act. See *id.* at 156, 167-191, 206-208. An addendum to that report described some of the difficulties that had been

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[3] Two problems caused particular concern. First, military records did not accurately indicate the location of individual soldiers on a given day, because soldiers within a company could be dispersed as much as 12 miles from the recorded company location. See C.A. App. 64, 125. Second, for many days there were no records at all, and many sprayings of Agent Orange were unrecorded. See *id.* at 45, 64-65, 59, 125.

encountered, and similarly warned that it might not be possible to carry out the Agent Orange exposure component of the overall epidemiological study required by the 1979 and 1981 Acts. See *id.* at 207-208. The Secretary's cover letter noted that leadership of the relevant congressional committees had recently asked, in light of the OTA's concerns, that no new major phase of the Agent Orange study, including contacting or examining study subjects, be undertaken until the OTA had approved a new study design and exposure assessment methodology. *Id.* at 208.

The Agent Orange Working Group (AOWG), a White House group formed to carry out the President's coordination responsibilities under the 1979 Act, convened a scientific subpanel to review the exposure assessment situation. C.A. App. 126. Based on that review, and on an independent pilot study, the subpanel concluded that the potential for misclassification of individual soldiers' exposure status was so great that it would be impossible to obtain valid results from any study in which exposure estimates were based solely on military records. *Ibid.*; see *id.* at 39, 59, 64-65. In June, 1986, the subpanel recommended that the Agent Orange study not be conducted without some independent method of verifying exposure assessments based on military records. *Id.* at 126.

That summer the CDC developed a new method of measuring directly the level of dioxin (the contaminant present in some Agent Orange that was thought most likely to cause human health effects). C.A. App. 127, 136F. That method allowed the CDC to gauge an individual's past exposure to Agent Orange by measuring the current level of dioxin, also known

as TCDD, in his blood.[4] *Ibid.* Using the new blood test, the CDC undertook a study, approved by the OTA and the AOWG scientific subpanel, designed to provide independent validation for one or more of the exposure estimation methods based on review of military records. *Ibid.*; see *id.* at 133-134C.

The TCDD validation study showed no meaningful association between Agent Orange exposure estimates derived from military records or from self-reporting and evidence of prior dioxin exposure derived from the new blood tests. C.A. App. 145; see also *id.* at 117-123, 135-145A. That result indicated that the investigators could not rely on military records to identify cohorts of veterans exposed and not exposed to dioxin. See, *e.g.*, *id.* at 120, 145. Nor did consultations with experts on military records and operations in Vietnam suggest any other method for identifying usable cohorts. *Id.* at 144. Based on those results, the CDC reluctantly concluded that it could not conduct a scientifically valid Agent Orange exposure study. *Id.* at 129-130.

After reviewing the TCDD validation study, the AOWG science panel, the VA's Department of Medicine and Surgery, and the OTA all agreed with the CDC's conclusion. See C.A. App. 66, 67-78, 152, 264-266; see also *id.* at 60-62, 79-86, 158-159. On the basis of that unanimous scientific advice, the Secretary made the final decision to cancel the Agent Orange exposure study. *Id.* at 284-285. On February 9, 1988, the Secretary notified Congress of the consensus that "no scientifically sound study [could] be undertaken." *Id.* at 262. The Secretary's letter noted that

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[4] TCDD stands for 2,3,7,8-tetrachlorodibenzo-p-dioxin. Pet. App. 4a n.3.

the other two studies proposed by the CDC's original protocol to implement the mandate of the 1979 and 1981 Acts were in progress, and that various similar research projects were underway or planned. *Id.* at 263.

On February 19, 1988, the Secretary submitted his third annual report under Section 307(b)(2) of the 1979 Act. C.A. App. 202-204, 217-231. That report again explained the reasons for termination of the Agent Orange exposure component of the overall epidemiological investigation. See *id.* at 202-204, 224-226. Two days earlier, the Secretary had brought to Congress's attention the availability of funds that had been appropriated for the conduct of the Agent Orange study, had noted that those funds would revert to the Treasury if not redesignated for other uses, and had suggested that, if Congress were to reappropriate the funds, "consideration might be given to support of the U.S. Air Force's * * * blood dioxin levels research or other research on Agent Orange and closely related subjects." *Id.* at 267-268. In November, 1988, Congress provided that

> [f]unds appropriated to the Veterans' Administration * * * and obligated through the Centers for Disease Control for a contract for the conduct of an epidemiological study relating to exposure of veterans to the herbicide known as Agent Orange shall, upon the cancellation of that contract, be available for obligation until September 30, 1989, in the amounts of—
>
> (1) $3,000,000 for payment of expenses of the Department of the Air Force in connection with blood tests of individuals who, while serving in the Air Force, participated in the

> spraying of Agent Orange in Vietnam during the Vietnam era; and
>
> (2) $1,000,000 for payment of expenses of a survey of scientific evidence, studies, and literature relating to health effects of possible exposure to toxic chemicals contained in herbicides used in the Republic of Vietnam during the Vietnam era, which survey shall be conducted by an independent scientific entity under contract to the Veterans Administration pursuant to a law enacted after the date of the enactment of this Act.

Veterans' Benefits Improvement Act of 1988, Pub. L. No. 100-687, Div. B, § 1201, 102 Stat. 4125.

3. In August, 1990, petitioners brought this suit seeking to compel the government to conduct the Agent Orange exposure study that had been cancelled in early 1988. The district court granted the defendants' motion for summary judgment and dismissed the case. Pet. App. 30a-49a. The court first determined that the action under review was the Secretary's final decision to terminate the Agent Orange exposure study (*id.* at 38a-40a), and largely denied petitioners' motion to supplement the administrative record (*id.* at 40a-43a). Having reviewed in detail the history of the VA's efforts to conduct the Agent Orange study (see *id.* at 32a-35a, 45a-46a), the court then concluded that "neither the scientific conclusions leading up to the VA's decision to terminate the study nor the [Secretary's] final decision were 'arbitrary and capricious' " (*id.* at 46a) within the meaning of the Administrative Procedure Act, 5 U.S.C. 706(2)(A). Finally, the court rejected petitioners' contention that the cancellation was

"otherwise not in accordance with law" (*ibid.*). Pet. App. 46a-47a. Noting the Act's requirement that the President assure that any study undertaken be scientifically valid, the court upheld as reasonable the Secretary's conclusion that his periodic reports to Congress fulfilled the requirements of Section 307(b)(2) of the 1979 Act, and that he therefore had the authority, under Section 307(a)(3) of the Act, to terminate the Agent Orange study in 1988 after determining that it could not be conducted in a scientifically valid manner. Pet. App. 46a-47a.

The court of appeals affirmed. Pet. App. 1a-27a. That court also reviewed the history of the Agent Orange exposure study at considerable length. *Id.* at 3a-12a. Like the district court, the court of appeals accepted the Secretary's interpretation of the statutory reporting requirement (*id.* at 13a-18a), and "conclude[d] that the Secretary satisfied his initial reporting obligation under § 307(b)(2) of the 1979 Act when he submitted a report to Congress on February 13, 1986, describing the results of efforts to carry out the epidemiological study" (*id.* at 18a). The court also rejected petitioners' contention that the Secretary had applied the wrong statutory standard in deciding to terminate the Agent Orange study. *Id.* at 18a-22a.

Finally, the court agreed with the district court that the Secretary did not act arbitrarily or capriciously in determining that the proposed Agent Orange exposure component of the overall epidemiological investigation required by the 1979 and 1981 Acts could not be carried out in a scientifically valid manner. Pet. App. 22a-27a. To the contrary, "[b]ased on the data available to [him] in February 1988, * * * the Secretary could reasonably conclude that it was impossible to identify groups of Vietnam veterans

who were similar except for their levels of dioxin exposure, as required for the cohort tests necessary to ascertain the health effects of dioxins through a scientifically valid Agent Orange Study." *Id.* at 26a-27a.

ARGUMENT

1. Petitioners argue (Pet. 16-22) that the Secretary violated a statutory mandate when he cancelled the Agent Orange exposure study component of the overall epidemiological investigation proposed by the CDC's initial 1983 protocol. The court of appeals correctly rejected that contention. Pet. App. 13a-18a.

Section 307(a)(1)(A) of the 1979 Act, as amended by the 1981 Act, required an epidemiological study of long-term human health effects that might have resulted from Vietnam veterans' exposure to Agent Orange or other herbicides, and particularly to any dioxin that was produced during the manufacture of those herbicides. See Pet. App. 52a. The study protocol was to be approved, and its implementation "monitor[ed]," by the Director of the congressional OTA, who was to advise Congress of his conclusions regarding the protocol's "scientific validity and objectivity." 1979 Act § 307(a)(2), 93 Stat. 1097; Pet. App. 53a. Similarly, Congress directed the President to coordinate the study required by the statute with other federal government research efforts concerning the human health effects of dioxin exposure, "[f]or the purpose of assuring that any [such] study carried out by the Federal Government * * * is scientifically valid and is conducted with efficiency and objectivity." 1979 Act § 307(c), 93 Stat. 1098; Pet. App. 55a. Finally, Congress called for annual reports from the Secretary describing "the results thus far

obtained under the study conducted" under Section 307(a)(1)(A), and provided that the study should be "continued for as long after the submission of the first report * * * as the [Secretary] may determine [to be] reasonable in light of the possibility of developing through such study significant new information on the long-term adverse health effects of exposure to dioxins." 1979 Act § 307(b)(2), 93 Stat. 1098; 1979 Act § 307(a)(3), 93 Stat. 1097, as amended by 1981 Act § 401(a)(2), 95 Stat. 1061; Pet. App. 54a.

These provisions make clear Congress's desire that the mandated and funded research be "scientifically valid," and that it lead, if possible, to "significant new information." In seeking to fulfill that mandate, the VA, through the CDC, initially proposed three separate studies, two of which have since been successfully completed. Pet. App. 5a & n.5. In the case of the Agent Orange exposure study at issue here, however, the CDC's proposed protocol explicitly recognized that "many of the proposed procedures" for identifying usable cohorts of exposed and unexposed veterans were "untested," and noted that, for that reason, "modification, [or] indeed even a recommendation not to proceed with an Agent Orange study, [might] be required after pilot study assessments." C.A. App. 107. The OTA's approval of the initial protocol was made in light of that reservation. See, *e.g.*, *id.* at 97; see also *id.* at 200-201; cf. Pet. 8 n.9.[5] It is implausible

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[5] In 1985, the OTA Director wrote to Senator Leahy of the Senate Appropriations Committee concerning OTA's "continuing review of progress" of the Agent Orange exposure study. C.A. App. 200-201. Among other things, that letter quoted the language cited above from the CDC's initial protocol, and noted that "[w]hen the original Agent Orange study design was approved by the OTA, there were still many

that Congress intended to require the Secretary to proceed with that study when, after years of concerted effort to develop and validate an acceptable final protocol, the CDC scientists working on the study, the OTA scientists charged with "approv[ing]" and "monitor[ing]" it, the science subpanel of the White House working group charged with "coordinat[ing]" all similar research and assuring its "scientific[] valid[ity,] * * * efficiency and objectivity," and the Secretary's own science advisors had all concluded that it could not be conducted in a scientifically valid manner. See pages 5-8, *supra*.

In arguing to the contrary, petitioners focus on the word "results" in Section 307(b)(2) of the 1979 Act. Pet. App. 16-21. They contend that the term "result" means only "the final product or conclusion of a process" (Pet. 17), and that Congress must have intended to require the Secretary to continue the Agent Orange exposure study until he could file at least one report under Section 307(b)(2) including "health results" (Pet. 19)—that is, health information collected from veterans—before he could terminate

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unanswered questions and uncertainties which only would be resolvable when representative data from the military records had been assembled." *Id.* at 200. In light of subsequent work with the available military records, the OTA believed that the "CDC should now be able to make some final decisions about study design and about the quality of the exposure data on which the study results will be based," and the OTA therefore "request[ed] a new statement of study design, incorporating, as necessary, new plans for exposure assessment." *Id.* at 200-201. Because the OTA would require more time "to consider [a] revised Agent Orange study protocol for approval," the Director urged that "no major new phase of the study should be undertaken before the new design and exposure assessment method are found acceptable." *Id.* at 201.

the study as unlikely to develop "significant new information." 1979 Act § 307(a)(3), 93 Stat. 1097; Pet. App. 54a. Since the time of his first report to Congress under Section 307(b)(2), however (see Pet. App. 14a n.11), the Secretary has construed the statute to require only a report on the "results thus far obtained" from the VA's good-faith effort to test, refine, and finalize the proposed but "untested" (C.A. App. 107) CDC protocol for the exposure study.

The court of appeals upheld that construction. Pet. App. 13a-18a. The court remarked (*id.* at 14a-15a) that the word "results" is "one of common parlance subject to multiple meanings," and the term is broad enough to include, for example, the problems identified (and reported to Congress) with the use of military records alone to identify exposed and unexposed veterans, and the conclusion of the TCDD validation study that current blood serum levels of dioxin bore no meaningful relation to any of the records-based exposure estimates. Alternatively, the Secretary satisfied Section 307(b)(2) when he reported periodically to Congress, in effect, that *no* "results" had "thus far [been] obtained under the study" in question, because of the methodological problems encountered in attempting to get the study underway. Petitioners' construction of Section 307, on the other hand, would apparently have required the Secretary to compile and report medical data about a large group of veterans ("health results"), even if it were clear that the study would ultimately conclude that those data could not be meaningfully analyzed, because it was impossible to divide the overall group reliably into exposed and unexposed cohorts.

The court of appeals carefully considered, and rejected, all of petitioners' statutory arguments. Pet.

App. 16a-18a. That decision does not conflict with the decision of any other court of appeals, and no such conflict is ever likely to arise (see Pet. 15); nor does it raise any legal issue of broad application beyond the particular statute at issue in this case. Cf. *Ticor Title Ins. Co.* v. *Brown*, 114 S. Ct. 1359, 1362 (1994) (per curiam); *Dobbs* v. *Zant*, 113 S. Ct. 835, 837 (1993) (Scalia, J., concurring in the judgment).

2. Petitioners argue (Pet. 21-22) that the court of appeals' reliance on *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), conflicts with this Court's "rule that interpretive doubt is to be resolved in the veteran's favor." *Brown* v. *Gardner*, 115 S. Ct. 552, 555 (1994). The two principles may not, in fact, conflict. See, *e.g.*, *Fishgold* v. *Sullivan Drydock & Repair Corp.*, 328 U.S. 275, 285 (1946) ("Our problem is to construe the separate provisions of the Act as parts of an organic whole and give each as liberal a construction for the benefit of the veteran *as a harmonious interplay of the separate provisions permits*.") (emphasis added). In all events, this would be an inappropriate case in which to resolve any conflict between them.

First, petitioners made no such argument in either court below. Second, and perhaps for that reason, neither court below addressed the issue, and this Court therefore would not have the benefit of those courts' views on the question, either in general or as related to the facts of this case. Third, all the cases that petitioner cites (Pet. 21) involve statutes providing easily identifiable benefits or protections for individual veterans. In this case, on the other hand, it is not clear why it would benefit veterans to force the Secretary to conduct a study that all the

government experts designated by Congress agreed would not yield valid results.

3. Petitioners argue (Pet. 23-30) that the Secretary's decision to cancel the Agent Orange exposure study was arbitrary and capricious. That claim cannot withstand review of the record in this case.

As the court of appeals correctly pointed out (Pet. App. 12a-13a), review of the Secretary's ultimate decision to cancel the exposure study is properly limited to determining whether the Secretary "examine[d] the relevant data" and then acted on the basis of a "rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of the United States, Inc.* v. *State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Moreover, "[g]iven the nature of the scientific expertise brought to bear on the issue of whether to continue the [CDC's exposure study], the court's review is at its most deferential." Pet. App. 13a, citing *Baltimore Gas & Elec. Co.* v. *Natural Resources Defense Council, Inc.*, 462 U.S. 87, 103 (1983). Finally, the court determined that, in light of the explicit discretion to terminate conferred on the Secretary under Section 307(a)(3) of the 1979 Act, "the scope of * * * review of the Secretary's decision to abandon one component of the [CDC's 1983 proposed overall protocol] is particularly limited." Pet. App. 22a.

In evaluating the Secretary's decision, the court of appeals reviewed in considerable detail the history of the VA's efforts to design and implement the exposure study, and of the Secretary's ultimate decision to terminate it. Pet. App. 5a-11a, 22a-27a; see also pages 4-8, *supra*. Petitioners' arguments, in this Court as in the courts below, amount to a challenge to technical conclusions unanimously reached, over a

period of several years, by the scientific advisors who considered the issue of study validity independently at the CDC, the OTA, the White House, and the VA. The record leaves no doubt that the Secretary's final decision to terminate the exposure study was neither unexamined nor irrational.

Finally, the record makes clear that Congress was fully apprised, on an ongoing basis, of the problems that were encountered in attempting to design and implement the Agent Orange exposure study. See, *e.g.*, pages 5-6, *supra*. Indeed, when they were informed by the OTA that exposure verification problems had proven difficult and perhaps intractable, the leaders of the relevant congressional committees themselves requested that " 'no new major phase of the study, including contacting or examining study subjects[,]' be undertaken until OTA ha[d] approved the new study design and exposure assessment methodology" that it was hoped could be developed. C.A. App. 208 (Secretary's letter transmitting first status report, quoting letter of January 10, 1986, from House Veterans' Affairs Committee leadership to the Secretary of Health and Human Services, and citing similar letter from Senate committee leadership to HHS and the President); see also note 5, *supra*.

It is therefore not surprising that, when the Secretary made his final decision to cancel the study, Congress took no action to countermand that decision. To the contrary, it accepted the Secretary's invitation to take the money previously allocated to the exposure study and reappropriate it for other, related uses. See pages 8-9, *supra*. Under those circumstances, the contention that the Secretary's decision has deprived veterans of a "chance Congress

intended" (Pet. 16) is better directed to Congress than to this Court.[6]

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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NOVEMBER 1995

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[6] Petitioners refer repeatedly to a recent report published by the National Academy of Sciences (NAS) (several years after the administrative decision at issue in this case) concerning the health effects of herbicides used in Vietnam. See, *e.g.*, Pet. 4 n.3. We are informed that, partly in response to that report, the VA recently engaged the NAS to develop and disseminate a request for proposals to create a "historic exposure reconstruction model for herbicides in Vietnam." The NAS's overall proposal contemplates future funding for evaluation of proposals received, selection of a group to develop such a model, oversight of the development process, and evaluation of any model ultimately developed. The VA's initial funding for this proposal indicates a continuing willingness to explore whether newly developed methodologies will now permit researchers to gather, in a scientifically valid manner, the sort of information originally sought by the 1979 and 1981 Acts.

Supreme Court, U.S.
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IN THE
Supreme Court of the United States
OCTOBER TERM, 1995

THE AMERICAN LEGION,
BILL ATWELL, CAROL DELANEY-RIDOLFI,
JULIO GONZALEZ, MAREL J. MACKI,
BEVERLY NEHMER and PAUL SUTTON,
Petitioners,

v.

JESSE BROWN, SECRETARY, DEPARTMENT OF VETERANS AFFAIRS; DONNA E. SHALALA, SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES; DAVID SATCHER, DIRECTOR, CENTERS FOR DISEASE CONTROL; RICHARD J. JACKSON, DIRECTOR, NATIONAL CENTER FOR ENVIRONMENTAL HEALTH; UNITED STATES OF AMERICA,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

PETITIONERS' REPLY BRIEF

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PETITIONERS' REPLY BRIEF

INTRODUCTION

As to the importance of the questions presented for review, what is most noteworthy about the government's opposition is what it does not dispute. The government does not deny that if, as the veterans argue, the government's conclusion that it was impossible to conduct a scientifically valid Agent Orange exposure study based on military records alone is "arbitrary and capricious", the study's cancellation could adversely affect huge numbers of people: as many as 245,162 Vietnam veterans, and, including their families, an estimated total of 612,905 people.

The government does not deny that an epidemiological study may be scientifically valid even with sizeable random misclassification, and that such a study would discover adverse health effects if they were strong enough. Further, the government does not deny that if the cancellation were vacated as "arbitrary and capricious", and the study conducted, it might discover sufficiently high statistical associations between likely exposure to Agent Orange and various diseases to require the Secretary's granting VA disability and death compensation for Vietnam veterans with those diseases, or their families, respectively.[1] Thus, the government does not deny that, if its study cancellation were held to be "arbitrary and capricious," [2] potentially tens of thousands of individuals might

[1] The government's completion of two other "discretionary" epidemiological studies evaluating possible associations between service in Vietnam and various diseases, Op. Cert. at 3-4, does not undermine the need for, or the importance of, conducting the mandatory study at bar. As the Secretary admits, of the three studies, only the canceled study "was designed as a direct investigation of the effects of exposure to Agent Orange." Op. Cert. at 4.

[2] The government prefers to avoid the question of what benefits the veterans might qualify for if this Court were to vacate the cancellation. Instead, it simply presumes that its scientists' conclu-

receive VA disability or death compensation benefits which they would otherwise not receive.

The government's effort to undercut this petition's importance by arguing that it does not "raise any legal issue of broad application beyond the particular statute at issue in this case[]," Op. Cert. at 15, is misconceived. Initially, resolving the *Gardner/Chevron* question whether, where statutes benefitting veterans are ambiguous, the ambiguity is to be resolved favorably to the veterans or to the agency, would apply to ambiguities in many statutes administered by the Secretary of Veterans Affairs beyond Pub. L. 96-151, *e.g.* 38 U.S.C. § 1101 *et seq.* (disability compensation), § 1301 *et seq.* (death compensation, § 1501 *et seq.* (pensions) and § 1701 *et seq.* (health care).

Similarly, if the Court were to elaborate the extent to which an agency decision based on scientific or technical conclusions must, to avoid being "arbitrary and capricious", contain reasoned explanations of how the agency applied the relevant scientific or technical principles to the facts found to reach its conclusion, that too would apply broadly to all federal departments and agencies which make such decisions, such as the Departments of Defense, Health and Human Services, and Labor and the Environmental Protection Agency. Thus, contrary to respondents' assertion, both of these issues would have "broad application" far beyond the statute at issue in this case.

Moreover, the government's premise that a case may only be important enough for this Court's review if it has impact beyond the statute at issue is unsupported by the cases cited, Op. Cert. at 15, and unsupportable. *Ticor Title Insurance Company v. Brown*, 114 S. Ct. 1359, 1362 (1994), which noted that "the posited constitutional question may be . . . of virtually no practical consequence in fact, except with respect to these particular litigants[]", in-

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sion that the study "would not yield valid results" is unimpeachable. See Op. Cert. at 15-16.

volved only six title insurance companies, 114 S.Ct. at 1360, and an unstated number of title insurance consumers in Arizona and Wisconsin. *Id.* at 1361. The other case cited, *Dobbs v. Zant*, 113 S.Ct. 835, 837 (1993) (Scalia, J., concurring in the judgment), involved only a single defendant in a capital case, 113 S.Ct. at 836-37, and the Court, in fact, granted certiorari.

The principle which Justice Scalia advocated, with Justice Thomas concurring, was that articulated by Justice Stevens: " '[i]t is not appropriate for this Court to expend its scarce resources crafting opinions that correct technical errors in cases of only local importance where the correction in no way promotes the development of the law.' *Anderson v. Harless*, 459 U.S. 4, 12, 103 S.Ct. 276, 280, 74 L.Ed.2d 3 (1982) (STEVENS, J., dissenting)." 113 S.Ct. at 837. Far from supporting the government, this principle helps the veterans since the statute whose violation is at issue here is by no means of only "local importance," but affects potentially tens, if not, hundreds, of thousands of people nationwide.[3]

Nor does the fact that VA recently contracted with the National Academy of Sciences "to develop and disseminate a request for proposals to create a 'historic exposure reconstruction model for herbicides in Vietnam[]'," Op. Cert. at 18 n.6, undermine the importance of this Court's deciding this case. Respondents have estimated that it would take approximately two to three years from now just to complete the development of a model. After that, it is speculative whether VA would ever use the model to conduct a large scale study like the Agent Orange exposure study mandated here, and if so, how many more years it would take to complete such a study. But Vietnam veterans are suffering and dying now of diseases

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[3] While the government avers that the decision below "does not conflict with the decision of any other court of appeals, ...", Opp. Cert. at 15, it never responds to the veterans' argument that this case is similar to a nationwide class action in which there would never be a conflict in the circuits.

believed due to Agent Orange exposure, without any VA disability or death compensation for most of the diseases suffered. Gathering health results under the mandated study is long overdue; this Court's review of this case is needed to make it possible for that to happen.[4]

THE VETERANS' HEALTH PROGRAMS IMPROVEMENT ACT CLAIM

a. The government's response to the veterans' arguments that, applying traditional tools of statutory construction, the clear intent of Congress was to require a report of health results before the Secretary could cancel the study consists, essentially, of one sentence: "The court of appeals carefully considered, and rejected, all of petitioners' statutory arguments." Op. Cert. at 14. Respondents' assertion cannot withstand scrutiny.

The court of appeals either never considered, or considered only superficially and incorrectly, various critical tools and canons of construction. We provide two examples. First, determining the meaning of the terms "results" and "progress" was central to construing the statutory provision at issue. This Court has taught that the tool to be used to begin this process is the dictionary. *E.g. MCI Telecommunications Corp. v. American Telephone and Telegraph*, 114 S.Ct. 2223, 2229 (1994). The proffered dictionary definitions of these two terms sharply distinguished between their respective meanings, strongly favoring petitioners' construction. "Result" is

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[4] Nor is the government's congressional inaction and partial reappropriations argument, Op. Cert. at 17-18, entitled to any weight. Insofar as the government hints that the cancellation decision was ratified by appropriation, the district court expressly rejected that very argument. Pet. App. 36a-37a. Insofar as the government suggests that it is not appropriate for aggrieved parties like the veterans here to seek judicial enforcement of a statute that has never been repealed, *see* Pet. App. 36a, because they must instead seek congressional enactment of a new statute reiterating what the law already requires, this Court has repudiated that view. *See Tennessee Valley Authority v. Hill*, 437 U.S. 153, 189-90 (1978).

defined as: "the conclusion or end to which any course or condition of thing leads, or which is obtained by any process or operation." Black's Law Dictionary, 1478 (4th ed. 1957). By contrast, "progress" is defined as: "movement toward a goal." The American Heritage Dictionary, 2nd College Ed., Houghton Mifflin 990 (1985).

The "conclusion or end" of the study was gathering information on health results. The court's construction of "results" of the study, the end of a process, as having been intended to mean merely movement toward conducting the study turned the dictionary definitions on their head. But, the court below refused to examine any dictionary. While the court said that it would have construed "results" differently if the word had a "[meaning] clear[ly] contrary," Pet. App. at 17a, to "progress", by refusing to look at dictionaries it prevented itself from finding out the "clear contrary meaning." [5]

Second, the court never considered what construction was most consistent with the statute's "purpose." That omission is particularly serious here because Pub. L. 96-151's fundamental purpose was to produce study results as to whether veterans likely exposed to Agent Orange disproportionately suffered adverse health effects. If the court had used that tool, it would have weighed heavily in favor of concluding that the "results" Congress wanted before it would allow the Secretary to cancel the study were initial *health* results.[6] The lower court's analysis did

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[5] Indeed, the VA Administrator himself recognized in his first report to Congress on the exposure study that his status report did *not* constitute a report of "results." He noted that the "results" (Congress sought) were "documentation of the study's [health] findings [which] are not yet available, nor will they be until data collection and analysis are completed." App. 207.

[6] Remarkably, the court never reconciles its conclusion that Congress intended to require the Secretary merely to submit a progress report with its concession that *Congress never even "consider[ed] the possibility that the study might not ultimately yield substantive health results. . . ."* Pet. App. 17a n.13 (Emphasis added).

not comport with this Court's principles for performing statutory construction.[7]

The government does not contest that the appellate court's alternative ruling that to read the statute as mandating a report of health results prior to cancellation would lead to "absurd results" depends entirely on the "accuracy," Pet. App. 18a, or legality, of the government's determination that it was impossible to do a scientifically valid study with military records alone. If, as the veterans argue, this government determination was "arbitrary and capricious," the government does not deny that that would nullify the lower court's "absurd results" holding.

b. In arguing that the *Gardner* and *Chevron* canons for resolving statutory ambiguities may never conflict, the government cites *Fishgold v. Sullivan Drydock & Repair Corp.*, 328 U.S. 275, 285 (1946) for the proposition that courts should " 'give each [provision of a statute] as liberal a construction for the benefit of the veterans *as a harmonious interplay of the separate provisions permits'* " (emphasis added by government), Op. Cert. at 15. However, this principle does not eliminate any conflict between *Gardner* and *Chevron*, and *Fishgold* is distinguishable.

In *Fishgold*, the Court found that the relevant statute's plain language provided protection for a veteran "against . . . loss of seniority by reason of his absence [but that n]o step-up or gain in priority can be fairly implied." 328 U.S. at 285-86. That is, the *Fishgold* statute did not present "interpretive doubt" within the meaning of *Brown v. Gardner*, 115 S.Ct. 552, 555 (1994), or "ambigu[ity]" within the meaning of *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 (1984).

By contrast, here, the appellate court treated the congressionally intended meaning of "results" as ambiguous,

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[7] See generally, Pet. at 17-21.

and, for that reason, deferred to the agency's "permissible construction" under *Chevron*. Pet. App. 14a. The *Gardner* canon, instead, would have resolved the "interpretive doubt" for the veterans.[8] Unlike *Fishgold*, this is a situation of ambiguity: "results" may not be construed both favorably to veterans, as satisfied only by a report of health results, and favorably to VA, as satisfied by a mere progress report. *Gardner* and *Chevron* cannot both control. There is an actual conflict.

Nor would this be "an inappropriate case in which to resolve any conflict. . . ." Op. Cert. at 15. That the precise argument as to the conflict between the *Gardner* and *Chevron* canons was not presented below does not make this Court's review inappropriate, because "[o]nce a federal claim is properly presented, a party can make any argument in support of that claim; parties are not limited to the precise arguments they made below." *Yee v. City of Escondido, Cal.*, 112 S. Ct. 1522, 1532 (1992). A "claim" is defined very broadly. *See Yee*, 112 S. Ct. at 1531-32 ("substantive due process" and "Fifth Amendment's Taking Clause" each constitutes a separate "claim"). Petitioners' argument that the *Gardner* canon

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[8] Insofar as the government is arguing that Pub. L. 96-151 is not the kind of statute to which *Gardner's* liberal construction for veterans canon applies because it does not provide "easily identifiable benefits or protections for individual veterans," Op. Cert. at 15, respondents err. The rationale for this canon does not turn on whether a statute's benefits for veterans satisfy some imaginary standard of "ease of identifiability", but on whether the statute was enacted for the purpose of protecting or benefitting veterans. *See, Fishgold*, 328 U.S. at 284-285; *Boone v. Lightner*, 319 U.S. 561, 575 (1943).

Pub. L. 96-151 was unquestionably enacted to benefit Vietnam veterans by discovering whether diseases they suffered were statistically associated with likely exposure to Agent Orange. If so, Congress was explicit about the benefits individual veterans with those diseases would receive: VA service connected disability and death compensation. *See* 38 U.S.C.A. § 527 note (b) (3). Thus, even if *Gardner* required that the statutory benefits be "easily identifiable", these are.

conflicts with, and should supercede, the *Chevron* canon is merely one argument in support of their statutory claim that the Secretary violated 38 U.S.C.A. § 527 note (a)(3), (b)(2) by canceling the study before reporting any health "results." Therefore, this argument did not need to have been presented below.[9]

THE ARBITRARINESS AND CAPRICIOUSNESS CLAIM

The government asserts summarily that the veterans' arguments that the government's decision to cancel the study was arbitrary and capricious "cannot withstand review of the record in this case." Op. Cert. at 16. What is most striking about this section of the government's opposition is that, in fact, it never identifies any portion of the administrative record which responds to either of petitioners' two actual arguments.

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[9] In any case, if this Court were to hold that the meaning of "results" was ambiguous, it would be a "predicate to an intelligent resolution", *Vance v. Terrazas*, 444 U.S. 252, 258-59 n.5 (1980), of whether the court below had properly disposed of the statutory claim to decide whether the ambiguity should have been resolved in favor of the veterans under *Gardner*, or in favor of the government under *Chevron*, as actually occurred. For this reason, also, the argument need not have been presented below. *See Vance*, 444 U.S. at 258-59 n.5; *Procunier v. Navarette*, 434 U.S. 555, 559-60 n.6 (1978).

Unlike the veterans' "arbitrary and capricious" claim, which, if successful, would result only in vacating the Secretary's cancellation and remanding the matter for reconsideration, their statutory claim would compel the VA to conduct the study at least to the stage of reporting initial health results, subject to the veterans also winning their arbitrariness claim so as to defeat "absurd results." If the canon conflict were not resolved, and the appeals court's decision on the statutory claim were simply affirmed based on *Chevron* deference, the veterans would lose their entire statutory claim, and thereby have no right to have the study conducted nor to receive any death and disability compensation that might ensue. Whereas, were the conflict addressed and *Gardner* held to control, the study would have to be conducted and the veterans would receive any ensuing compensation.

Specifically, the government never cites any record explanation for its conclusion that the military records' misclassification risk was so high that, absent independent verification, it would make the study scientifically invalid; it does not dispute that the sole record explanation is the Subpanel's "feelings." [10] Nor do respondents ever address how the Subpanel's "feelings", by itself, could constitute a "reasoned explanation" for this pivotal conclusion sufficient to avoid rendering the conclusion "arbitrary and capricious." [11]

Similarly, the government never cites any portion of the record which demonstrates that, in reaching the above conclusion, it considered the relevant scientific criteria for determining whether any study's misclassification risk is so severe that it destroys the study's scientific validity. Neither do respondents ever deny that: such scientific principles or criteria exist; for Administrative Procedure Act purposes, they are "relevant factors" which the government legally had to have considered before determining whether this study's misclassification risk was so great it would invalidate the study; and respondents' failure to have considered these "relevant factors" rendered their conclusion "arbitrary and capricious."

While the government fails to rebut the veterans' specific legal arguments, it does confirm the arguments'

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[10] The government never takes issue with the veterans' showing, Pet. at 26-28, that none of the three grounds on which the D.C. Circuit relied, in fact, substantiated the Subpanel's "feelings."

[11] What the D.C. Circuit recently recognized in *Dickson v. Secretary of Defense*, Nos. 94-5190 and 94-5227 (Consolidated), —— F.2d —— (Oct. 31, 1995) (Slip Opinion at 14) is equally applicable here: "an agency's explanation must minimally contain 'a rational connection between the facts found and the choice made.' *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983) (citing *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962). . . . *Because the* [*agency*] *failed to provide anything approaching a reasoned explanation for its decisions, we hold that the . . . determinations were arbitrary and capricious.*" (Emphasis added) A copy of this decision is being lodged with the Clerk's Office.

underlying factual premises. The government implicitly concedes that the critical determination on which the cancellation decision ultimately rested was "the subpanel['s] conclu[sion] that the potential for misclassification of individual soldiers' exposure status was so great that it would be impossible to obtain valid results from any study in which exposure estimates were based solely on military records." Op. Cert. at 6. It was because of this conclusion that "the subpanel recommended that the Agent Orange study not be conducted without some independent method of verifying exposure assessments based on military records." *Id.* And it was the inability of the "TCDD validation [blood] study [or] any other method", *id.* at 7, to provide such independent verification which ultimately caused the government, including the Secretary, to decide to cancel the Agent Orange exposure study.

In short, the decision to cancel the study rested on the conclusion that the military records' misclassification risk was so great that a study based solely on military records whose accuracy had not been independently verified could not be scientifically valid. Whether or not the Secretary's scientific advisors were "unanimous" in this conclusion,[12] the fundamental fact is that neither they nor the Secretary ever gave any reasoned explanation for it. Zero, plus zero, plus zero, plus zero is still zero; the emperor has no clothes. Because the conclusion was itself "arbitrary and capricious," the decision to cancel was "arbitrary and capricious," and should be set aside.

CONCLUSION

For the foregoing reasons, and those stated in the petition, the petition for a writ of certiorari should be granted.

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[12] Compare Op. Cert. at 16 with Pet. at 26-27 and n.27.

Respectfully submitted,

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